UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF ILLINOIS

EARSTERN DIVISION

CITY OF LAKELAND EMPLOYEES PENSION PLAN, Individually and on Behalf of All Others Similarly Situated, Plaintiff, vs. BAXTER INTERNATIONAL INC., et al., Defendants.	Case No. 1:10-cv-06016 CLASS ACTION DEMAND FOR JURY TRIAL

AMENDED CONSOLIDATED CLASS ACTION COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS

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1. Lead Plaintiff National Elevator Industry Pension Fund ("Plaintiff"), individually and on behalf of a proposed class (the "Class") of all purchasers of the publicly traded common stock of Baxter International Inc. ("Baxter" or the "Company") between June 10, 2009 and May 3, 2010, inclusive (the "Class Period"), by and through its undersigned counsel, brings suit against Baxter, Robert L. Parkinson, Jr. ("Parkinson"), Robert M. Davis ("Davis), and Mary Kay Ladone ("Ladone") (Baxter, Parkinson, Davis, and Ladone are sometimes collectively referred to as "Defendants").[1]

2. Plaintiff seeks remedies under the Securities Exchange Act of 1934 (the "Exchange Act") as a result of the fraudulent scheme undertaken by Defendants and the economic loss suffered when the true facts were partially revealed to the public through a series of disclosure events. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§78j(b) and 78t(a), and Rule 10b-5 promulgated thereunder, 17 C.F.R. §240.10b-5.

I. INTRODUCTION AND NATURE OF THE ACTION

3. Baxter's 2009 Annual Report to its shareholders begins with "A Conversation with Robert L. Parkinson, Jr.," during which the Company's Chairman of the Board and Chief Executive Officer ("CEO") provided responses to a series of questions about the Company and its future business prospects. When asked to what he attributed Baxter's ability "to deliver strong results despite a challenging economic environment," Parkinson responded, in part:

> While no company is immune to the effects of the global economic environment, we benefit from our diversified healthcare model, strong market positions and the medically necessary nature of our products. Virtually everything we develop, produce and market can mean the difference between life and death for a patient.

[1] Plaintiff files this Amended Consolidated Class Action Complaint for Violation of the Federal Securities Laws with the written consent of Defendants and pursuant to the parties' Joint Stipulated Order Regarding Filing of Amended Consolidated Class Action Complaint and Briefing on Defendants' Motion to Dismiss [Doc. 71].

> Our products that treat chronic, life-threatening diseases such as hemophilia, end-stage renal disease and primary immune deficiency, or are used in critical care, intensive care and other acute-care settings. ***As a result, we have not experienced a meaningful impact on demand for our products***. . . .

4. The truth, however, required a far different answer. Parkinson and, by extension, Baxter should have revealed the Company's true state of affairs: that Baxter's ongoing failure and known inability to remediate its Colleague Volumetric Infusion Pump (the "Colleague") for at least several years would cost the Company dearly; and that demand for key products in the Company's BioScience division (its largest revenue generator) had declined substantially in the wake of market share loss and disruption stemming from the collapse of a merger between Baxter's two largest competitors, which also exposed Baxter's anticompetitive behavior designed to manipulate and control supply and demand for various plasma-derivative products.

5. The collapse of the merger and the revelation of Baxter's iron-fisted control over the plasma market caused the Company, unbeknownst to the investing public, to lose market share, experience a loss in demand, and suffer a contraction in profit margins that resulted in diminished financial results in its critical BioScience business. Defendants, however, insisted to the market throughout the Class Period that the Company was "continu[ing] to see robust growth in demand" that would "drive revenue growth approximately 10 percent," and worked to convince the market that "the fundamentals continue to remain very solid and our confidence in this business is ***unchanged***." For example, on July 16, 2009, Parkinson assured the market that the Company "continue[d] to see strong underlying fundamentals and robust growth across [its] plasma portfolio." Likewise, on October 15, 2009, Parkinson again assured the market that there was "no indication at all that . . . we're losing market share and we don't plan on losing market share." Put simply, Defendants continuously assured the market, in no uncertain terms, that the Company would experience future growth, continued strong demand, and expanding margins.

6. Defendants also misled the market as to the Company's ongoing remediation efforts for one of its Medical Delivery products – the Colleague infusion pump – which is used to mechanically infuse solutions and drugs into patients intravenously at specified rates. In 2006, Baxter entered into a consent decree ("Consent Decree") with the United States Food and Drug Administration ("FDA") that required remediation of numerous and potentially life threatening defects in the hundreds of thousands of Colleague pumps sold by Baxter. The Consent Decree, which was signed by Baxter and Parkinson (individually), also required the Company to address and resolve several serious design flaws and internal quality and control deficiencies the FDA concluded contributed to the Colleague's repeated failures in actual clinical use.

7. At all times, Defendants assured the market that Baxter was remediating the Colleague and engaged in an active and positive dialogue with the FDA related to the Company's remediation efforts. For example, on June 10, 2009, Defendants told the market that the Company "continue[d] to be committed to remediating [the Colleague]. . . ." Similar statements were made on September 16, 2009, when Parkinson reaffirmed the Company had "remediated well over 100,000 devices in the U.S." and that the Company was looking to "get that resolved certainly in 2010."

8. Defendants' scheme worked, and as they raised the Company's 2009 guidance to deflect any concerns about the health of the plasma market, Defendants were able to artificially elevate the price of Baxter common stock to $61.71 per share by January 14, 2010, an increase of 33% over its price at the start of the Class Period.

9. Unbeknownst to the market, Defendants were in the midst of orchestrating a two-tiered fraud. First, Defendants knew Baxter was losing plasma-derivative products market share, revenue, and that improvements in the BioScience business' gross margins were not sustainable because the Company was experiencing declining demand and had, at least in part, lost its ability to manipulate supply and to control pricing following the failed merger of its two largest competitors.

10. Second, the Company was grossly incapable of (and largely uninterested in) remediating the Colleague. Throughout the Class Period, Defendants knew the Company was nowhere near completing its remediation efforts, and that it was simply not capable of remediating the Colleague in 2010. As demonstrated throughout this Complaint, the reality of Baxter's conflicts with the FDA regarding the remediation of the Colleague stands in stark contrast to Baxter's public statements with respect to the Colleague and demonstrates Defendants' knowledge that Baxter had not submitted a remediation plan for the triple channel Colleague pump nor was it moving as expeditiously towards remediating the single channel Colleague pump as the FDA requested, and was incapable of reaching a satisfactory remediation.

11. Indeed, prior to and throughout the Class Period, the FDA repeatedly told Baxter and Parkinson that the Company's remediation plans were unacceptable, would take too long, and would require clinical data before they could be implemented. Despite this, and despite its lack of any clinical data and numerous internal quality deficiencies, as well as Defendants' express knowledge that the FDA kept asking for a clinical study in support of a new remediation submission and for the timeframe involved in collecting clinical data, on April 8, 2010, the Company – without telling the market – submitted a proposed correction schedule to the FDA. The proposed correction schedule stated that Baxter "did not plan to begin the latest round of corrections to the adulterated and misbranded pumps until May 2012," and that Baxter did "not anticipate completion of the proposed corrections until 2013," some seven years after Baxter and Parkinson signed the Consent Decree. Completely fed up with Baxter's ongoing Colleague ineptitude, on April 30, 2010, the FDA sent a letter to Baxter ordering the Company to "recall and destroy" all of its Colleague pumps "currently in use in the United States" based on the Company's "longstanding failure to correct many serious problems with the pumps." The FDA also ordered Baxter to provide refunds to customers or replace Colleague pumps at "no cost to customers." The FDA confirmed that it had received more than

56,000 reports of adverse events associated with the use of infusion pumps, including reports of serious injuries and more than 500 deaths.

12. Defendants' fraud on the investing public unraveled quickly through two disclosures to the market that occurred less than two weeks apart. On April 22, 2010, the Company reported its first quarter 2010 financial results, lowering its revenue and earnings outlook for 2010. Defendants revealed, contrary to their consistently false statements throughout the Class Period, that due to continuing pressures in its critical plasma-derivative products business, including a loss in market share, as well as the impact of healthcare reform legislation, the Company was reducing its revenue guidance for 2010 to revenue growth in the range of 1% to 3%, down from a previous range of 5% to 7%. Specifically, the Company disclosed it was reducing its revenue guidance for its plasma-derivative products business from growth in the mid-to-high-single digit range to a ***decline*** in the mid-single-digit range and it was reducing its revenue guidance for antibody therapy products from growth in the mid-single digit range to a ***decline*** in the 10 percent to 15 percent range.

13. On this partial disclosure of Baxter's true financial condition and future business prospects, the price of its stock collapsed $7.82 per share to close at $51.13 per share on April 22, 2010, a one-day decline of more than 13% on volume of more than 50 million shares traded – more than 13 times the average three-month daily trading volume. The sudden drop represented the largest one-day decline in the Company's stock price in more than seven years.

14. Then, on May 3, 2010, the last day of the Class Period, Baxter revealed that the FDA had ordered it to not only recall, but destroy, all Colleague pumps in the United States healthcare system, and to pay full refunds to any persons, companies, or institutions that bought a Colleague pump in the United States. Baxter told investors that the Company anticipated taking a special charge of ***$400-$600 million*** in the first quarter 2010 "for the reasonably estimable cost of the

recall." In a separate press release, the FDA indicated the device-destruction recall was necessary due to the Company's "longstanding failure to correct many serious problems with the pumps."

15. As a result of this additional partial disclosure, the price of Baxter stock fell again, declining $2.42 per share, more than 5% on unusually heavy trading volume to close at $45.08 on May 4, 2010.

16. As a result of Defendants' false and misleading statements and failure to disclose highly material information to the market during the Class Period, the price of Baxter stock was artificially inflated. When the truth about the Company's financial condition and future business prospects was revealed, that artificial inflation was removed and the price of Baxter stock fell by 27% from its Class Period high. These drops removed the artificial inflation from the price of Baxter stock, causing real economic loss to investors who purchased the stock during the Class Period.

II. JURISDICTION AND VENUE

17. This Court has jurisdiction over the subject matter of this action pursuant to §27 of the Exchange Act, 15 U.S.C. §78aa, and 28 U.S.C. §1331.

18. Venue is proper in the Judicial District pursuant to §27 of the Exchange Act, 15 U.S.C. §78aa, and 28 U.S.C. §1391(b). In addition, the causes of action asserted herein occurred and/or accrued, among other places, in this District. At all times relevant to this action, Baxter was headquartered in this District, and many of the acts and transactions alleged herein, occurred in substantial part in this District.

19. In connection with the acts, conduct, and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mails, interstate telephone communications, and the facilities of the national securities markets.

III. THE PARTIES

20. Court-appointed Lead Plaintiff National Elevator Industry Pension Fund purchased Baxter securities on the open market during the Class Period, as set forth in its certifications previously filed with the Court.

21. Defendant Baxter, founded in 1931, is a Delaware corporation with its principal place of business located at One Baxter Parkway, Deerfield, Illinois 60015.

22. Defendant Parkinson is, and at all relevant times was, Chairman of the Board, President, and CEO of Baxter.

23. Defendant Davis was, at all relevant times, Chief Financial Officer ("CFO") and Corporate Vice President of Baxter.

24. Defendant Ladone was, at all relevant times, Corporate Vice President of Investor Relations of Baxter.

IV. THE INDIVIDUAL DEFENDANTS' ACCESS TO CRITICAL INFORMATION

25. Parkinson, Davis, and Ladone (collectively, the "Individual Defendants") were privy to confidential and proprietary information concerning Baxter, its operations, finances, financial condition, and present and future business prospects. The Individual Defendants also had access to material adverse non-public information concerning Baxter, as discussed in detail below. Because of their positions with Baxter, the Individual Defendants had access to non-public information about its business, finances, products, markets and present and future business prospects via access to internal corporate documents, conversations and connections with other corporate officers and employees, attendance at management and board of directors meetings and committees thereof and via reports and other information provided to them in connection therewith. Because of their possession of such information, the Individual Defendants knew or were severely reckless in disregarding the fact that

adverse facts specified herein had not been disclosed to, and were being concealed from (in order to mislead), the investing public.

26. Throughout the Class Period, the Individual Defendants were able to, and did, control the contents of the Company's SEC filings, reports, press releases, and other public statements. The Individual Defendants were provided with copies of, reviewed and approved, and/or signed such filings, reports, releases, and other statements prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. The Individual Defendants were also able to, and did, directly or indirectly, control the conduct of Baxter's business, the information contained in its filings with the SEC, and its public statements. Moreover, the Individual Defendants made or directed the making of affirmative statements to the investing public, and participated in meetings, conference calls, and discussions concerning such statements. Each of the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations that were being made were then false and misleading. As a result, each of the Individual Defendants is responsible for the accuracy of Baxter's corporate releases detailed herein and is therefore responsible and liable for the misrepresentations and omissions contained therein.

27. The Individual Defendants are liable as direct participants and co-conspirators with respect to the wrongs complained of herein. In addition, the Individual Defendants, by reason of their status as senior executive officers and/or directors, were "controlling persons" within the meaning of §20 of the Exchange Act and had the power and influence to cause the Company to engage in the unlawful conduct complained of herein. Because of their positions of control, the Individual Defendants were able to and did, directly or indirectly, control the conduct of Baxter's business.

28. The Individual Defendants, because of their positions with the Company, controlled and/or possessed the authority to control the contents of its reports, press releases and presentations to the investing public. The Individual Defendants were provided with copies of the Company's reports and press releases alleged herein to be misleading, prior to or shortly after their issuance, and had the ability and opportunity to prevent their issuance or cause them to be corrected. Thus, the Individual Defendants had the opportunity to commit the fraudulent acts alleged herein.

29. As senior executive officers and/or directors and controlling persons of a publicly traded company whose common stock and other securities were, and are, registered with the SEC pursuant to the Exchange Act, and whose shares traded on the New York Stock Exchange ("NYSE") and governed by the federal securities laws, the Individual Defendants had a duty to disseminate promptly accurate and truthful information with respect to Baxter's financial condition and performance, growth, operations, financial statements, business, products, markets, management, earnings and present and future business prospects, to correct any previously issued statements that had become materially misleading or untrue, so that the market price of Baxter's common stock would be based upon truthful and accurate information. The Individual Defendants' misrepresentations and omissions during the Class Period violated these specific requirements and obligations.

30. The Individual Defendants are liable as primary participants in a fraudulent scheme and wrongful course of business which operated as a fraud or deceit on purchasers of Baxter common stock by disseminating materially false and misleading statements and/or concealing material adverse facts. The fraudulent scheme employed by the Individual Defendants was a success, as it: (i) deceived the investing public regarding Baxter's prospects and business; (ii) artificially inflated the price of Baxter common stock; and (iii) caused Plaintiff and other members of

the Class to purchase Baxter common stock at inflated prices (which artificial inflation came out of the stock when the relevant truth regarding the true financial condition of Baxter was revealed).

V. CLASS ACTION ALLEGATIONS

31. Plaintiff brings this action as a class action pursuant to Federal Rules of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased the common stock of Baxter during the Class Period. Excluded from the Class are Defendants, the officers and directors of the Company, members of their immediate families and their legal representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest.

32. Because Baxter has millions of shares outstanding, and because the Company's shares were actively traded on the NYSE, members of the Class are so numerous that joinder of all members is impracticable. According to Baxter's SEC filings, as of March 31, 2010 (shortly before the close of the Class Period), Baxter had approximately 600 million shares of common stock outstanding. While the exact number of Class members can only be determined by appropriate discovery, Plaintiff believes that Class members number at least in the thousands and that they are geographically dispersed.

33. Plaintiff's claims are typical of the claims of the members of the Class because Plaintiff and all of the Class members sustained damages arising out of Defendants' wrongful conduct complained herein.

34. Plaintiff will fairly and adequately protect the interests of the Class members and has retained counsel experienced and competent in class actions and securities fraud litigation. Plaintiff has no interests that are contrary to or in conflict with the members of the Class it seeks to represent.

35. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy, since joinder of all members is impracticable. Furthermore, as the damages suffered by individual members of the Class may be relatively small, the expense and

burden of individual litigation make it impossible for the members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

36. Questions of law and fact common to the members of the Class predominate over any questions that may affect only individual members, in that Defendants have acted on grounds generally applicable to the entire Class. Among the questions of law and fact common to the Class are:

(a) Whether Defendants violated the federal securities laws as alleged herein;

(b) Whether Defendants' publicly disseminated press releases and statements during the Class Period omitted and/or misrepresented material facts;

(c) Whether Defendants breached any duty to convey material facts or to correct material facts previously disseminated;

(d) Whether Defendants participated in and pursued the fraudulent scheme or course of business complained of;

(e) Whether Defendants acted willfully, with knowledge or severe recklessness, in omitting and/or misrepresenting material facts;

(f) Whether the market prices of Baxter common stock during the Class Period were artificially inflated due to the material nondisclosures and/or misrepresentations complained of herein; and

(g) Whether the members of the Class have sustained damages as a result of the decline in value of Baxter's stock when the truth was revealed and the artificial inflation came out and, if so, what is the appropriate measure of damages.

VI. CONFIDENTIAL WITNESSES

37. Plaintiff makes the allegations herein, concerning the falsity of Defendants' statements and the scienter of the Individual Defendants, based upon the investigation undertaken by Plaintiff's counsel, which investigation included analysis of publicly available news articles and reports, public filings, securities analysts' reports and advisories about Baxter, interviews of former employees of Baxter, press releases and other public statements issued by the Company, and media reports about the Company. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

38. Moreover, the allegations made herein are supported by the first-hand knowledge of nine confidential witnesses ("CWs"). These informants include many former employees of Baxter who were employed during the Class Period and provided facts from various departments of the Company. As detailed below, the CWs each served in positions at Baxter that provided them with access to the information they are alleged to possess.

39. Confidential Witness 1 ("CW 1") was employed by Baxter for approximately 14 years until December 2009. CW 1 initially worked in the Company's Renal division, but beginning in 2006, CW 1 worked as a Document Manager in the Company's "change control" office located in the Baxter's Round Lake, Illinois' corporate office. During the last two years of CW 1's employment, she/he reported to Tamara Jordan ("Jordan"), who reported to Vice President of Quality Systems Joseph Seiner ("Seiner"). When Seiner was reassigned to the newly created Design Assurance division in August 2009, he was replaced by Michael Murphy ("Murphy"). Both Seiner and Murphy reported to Cheryl White ("White"), who served as Vice President of the Company's entire Quality organization. CW 1 was responsible for managing change control projects for the Quality department within Global Infusion Systems, including implementing procedures for document management and review as it related to both quality systems and the Colleague pump.

Among other things, CW 1 has knowledge regarding the Company's languishing remediation efforts for the Colleague pump and the Company's lack of "design traceability," which meant that Baxter was incapable of tracing the design evolution of its Colleague pumps.

40. Confidential Witness 2 ("CW 2") was employed with Baxter as a Software Analyst/Validation Analyst in the Company's Round Lake, Illinois facility from approximately October 2009 through July 2010. CW 2 reported to Quality Manager Scott Evans ("Evans"), who reported to Julius Aviza, the Director of Quality. CW 2 was tasked with reviewing "test scripts" for testing performed on Colleague pumps by the Company's engineering and quality control employees. CW 2 was responsible for the accuracy of the test scripts and ensuring that documents relating to the testing and validations were organized, logical and contained correct data for submission to the FDA. As such, CW 2 has knowledge concerning the Company's Colleague remediation efforts, as well as information relating to testing, data and results for tests performed on the Colleague pumps.

41. Confidential Witness 3 ("CW 3") worked for Baxter from 1981 until 2009 in a variety of positions. From 1997 through 2006, CW 3 worked as a Pump Sales Representative and then, in 2006, CW 3 transitioned to work as an IV Therapy Sales Representative. CW 3's sales territory included western Virginia, as well as parts of West Virginia and western Maryland. As an IV Therapy Sales Representative, CW 3 reported to Regional Manager Charles Gregory ("Gregory"), who reported to Area Manager Craig Prather ("Prather"). Among other things, CW 3 has knowledge concerning problems with the Colleague pump, related recalls, and the Consent Decree.

42. Confidential Witness 4 ("CW 4") worked for the Company as an Engineer in Infusion Pump Development for approximately four years, until August of 2010, in the Company's Deerfield, Illinois facility. During her/his first three years of employment, CW 4 worked in New Product Development seeking to develop new types of infusion pumps. Then, in 2009, CW 4 began working

on the Colleague pump as part of the Company's last minute scramble to comply with the FDA Consent Decree. As such, CW 4 has knowledge regarding the Company's delay and minimal effort to comply with the Consent Decree. Among other things, CW 4 has information concerning an "all hands on deck" meeting held at Baxter in late 2009 where all members of the Infusion Pump Development team were told that they were all to begin working on the Colleague pump in an effort to comply with the Consent Decree.

43. Confidential Witness 5 ("CW 5") was employed by Baxter from June 2008 through August 2010 as the Operations Manager of the Company's Plasma Collection Center in Elkhart, Illinois. CW 5 was hired to open the facility, which required her/him to work with the FDA in order to obtain required licensing. CW 5 was also responsible for coordinating marketing of the facility to the community. Once the facility opened, CW 5 was tasked with operating the facility and overseeing its approximately 40 employees. CW 5 reported to Regional Manager Paul Bray ("Bray"), who reported to the Division Director of Operations Scott Ehrmantrout ("Ehrmantrout") who, in turn, reported to BioLife Vice President Dennis Young ("Young"). Among other things, CW 5 has knowledge concerning the Company's manipulation of blood plasma supply, including the various "levers" Baxter would use in order to drive down blood plasma collections.

44. Confidential Witness 6 ("CW 6") was employed by Baxter from the end of July 2006 until January 2010 as Principal Engineer for Baxter's Global Infusion Systems division at the Company's Round Lake, Illinois facility. CW 6 worked in the software testing group as a Test Lead for both existing infusion pumps and infusion pumps under development. As a Test Lead, CW 6 was responsible for designing and running tests, as well as overseeing a staff of engineers. CW 6 recalled that during CW 6's tenure at the Company, there was heavy management turnover within Global Infusion Systems. Specifically, CW 6 was originally hired and supervised by Michelle Keyzer ("Keyzer"), a Manager within Global Infusion Systems. Keyzer hired Jose Antonio Rivera

("Rivera") a short time later and CW 6 reported to Rivera, who reported to Keyzer. Keyzer reported, for a time, to Richard De La Cruz ("De La Cruz"), a Director within Global Infusion Systems. De La Cruz, who left the Company prior to January 2010, reported to the Vice President of Global Infusion Systems, another position that had a significant amount of turnover. In July 2006, the Vice President of Global Infusion Systems was Rich Mussman, who left Baxter toward the end of 2006 and was replaced by Steve Lawrence, who, in turn, left around November 2007 and was replaced by Tim Robinson for a short time. Thereafter, the Company had two Vice Presidents leading Global Infusion Systems, Ross Krogh ("Krogh"), who led the group in 2008, and Daniel Khalili ("Khalili"), who was brought in by Krogh in mid-2008. Khalili (and Krogh, to some extent) reported directly to Peter Arduini ("Arduini"), then Corporate Vice President and President of the Medication Delivery division. Among other things, CW 6 has knowledge concerning the Company's inability to remediate the Colleague pump, including how remediating the Colleague did not become a priority until several years after the issuance of the Consent Decree, in August or September 2009, as well as information concerning the disorganization that was prevalent within the Company. CW 6 also has knowledge concerning how after the Company refocused its efforts on the Colleague in late 2009, there were daily morning meetings attended by all Global Infusion Systems managers and engineers working as leads on the remediation efforts.

45. Confidential Witness 7 ("CW 7") worked for Baxter from approximately May 2006 until mid-2008 as the Executive Assistant to former BioScience Division President Joy Amundson ("Amundson"), who reported directly to Parkinson. As Amundson's Executive Assistant, CW 7 was responsible for creating the report that Amundson used, as the BioScience Division President, to make presentations at Monthly Management Meetings. These reports included, among other things, breakdowns of financial information by each of the five business lines within the BioScience business, including by geographic location. In addition to this report, CW 7 also helped prepare an

80-page Power Point presentation for Amundson that was used to help Amundson explain the reports in further detail. In addition to the Monthly Management Meetings, CW 7 also has knowledge of the Weekly Management Call held every Monday morning at 8:00 a.m., Central Standard Time, which was attended by the same Company executives. CW 7 has knowledge of issues addressed by the Company at its internal meetings, the Company's financial information, as well as Parkinson's knowledge of these matters.

46. Confidential Witness 8 ("CW 8") was employed by Baxter from April 2008 to December 2009. CW 8 initially worked as a Manager in Clinical Services, a department within Global Infusion Systems, and was later promoted to the Senior Manager position. CW 8 was hired to work on the Company's Elizabeth infusion pump, but in mid-2009, CW 8 was reassigned to work on the Colleague pump as part of the Company's remediation efforts tied to the Consent Decree with the FDA. CW 8's responsibilities involved working with engineers in the Research & Development division of Global Infusion Systems and included review of proposals from engineers working on the Elizabeth infusion pump, and later the Colleague pump, to decide whether the proposals would be acceptable from a clinical perspective, meaning a doctor-patient setting. Among other things, CW 8 has direct knowledge concerning the Company's Colleague remediation efforts during the Class Period.

47. Confidential Witness 9 ("CW 9") originally worked for Baxter in the 1980s and 1990s, and then returned to work for the Company from 2005 until August 2009. In CW 9's most recent employment with Baxter, CW 9 initially served as a Senior Director for Renal Research and Development, and reported to Vice President of Research and Development Rohit Vishnoi ("Vishnoi"). When Vishnoi left Baxter following Thanksgiving in 2008, CW 9 was elevated to replace Vishnoi on an interim basis. Vishnoi and, subsequently, CW 9 worked for Renal Division President Bruce Migillivray ("Migillivray"), and reported to Executive Vice President of Research

and Development Bob Armstrong ("Armstrong"). Among other things, CW 9 has information concerning the close working relationship between Baxter's Renal and Medication Delivery businesses, and the operation, function, and failure of the Company's Design Center of Excellence, which was created in 2004 or 2005 to oversee quality for the production of all medical devices across the Company. CW 9 also has information concerning the software failures in the Colleague pumps, the Company's relationship with the FDA as it related to Baxter's infusion pumps, and the Company's knowledge in early 2009, at the latest, that it would have a very difficult time submitting any new fixes to the FDA for the Colleague pump. CW 9 also has knowledge that Parkinson had very candid conversations with McGillivray regarding ongoing issues with the Colleague pumps.

VII. FORMER FDA EMPLOYEES

48. In addition to the foregoing Confidential Witnesses, the allegations herein are based on the first-hand accounts of two former FDA employees with direct knowledge of Baxter's efforts to comply with the Consent Decree, including the Company's Colleague remediation efforts and the insufficiency of those efforts. These two former FDA employees consulted with Plaintiff and provided detailed facts and information concerning communications between the FDA and Baxter, Defendants' knowledge of those communications, and the Company's complete failure to satisfy even the most basic requirements of the Consent Decree. These facts clearly demonstrate that Defendants' Class Period statements regarding the Colleague were false and misleading when made.

49. Specifically, Plaintiff consulted with Timothy A. Ulatowski ("Ulatowski"), who worked for the FDA for approximately 36 years until he retired on January 1, 2011.[2] From January

[2] Attached hereto as ***Exhibit "A"*** is a true and correct copy of the Declaration of Timothy A. Ulatowski in Support of Lead Plaintiff's Amended Consolidated Class Action Complaint for Violation of the Federal Securities Laws (the "Ulatowski Declaration"). As set forth in the Ulatowski Declaration and herein, Baxter and its high-ranking representatives, including Parkinson, had actual knowledge of the Company's inability to comply with the terms and conditions of the Consent Decree, and that Defendants' Class Period statements

2003 until September 2010, Ulatowski served as the FDA's Director of the Office of Compliance in the Center for Devices and Radiological Health (the "CDRH").[3] Between September 2010 and his retirement from the FDA, Ulatowski held the position of Senior Advisor for Enforcement. As the Director of the Office of Compliance in the CDRH, Ulatowski reported to the Director of the CDRH, Dr. Daniel Schultz ("Dr. Schultz"), from April 2004 until approximately 2009, when Dr. Schultz resigned from the FDA. In approximately September 2009, Dr. Jeffrey Shuren ("Dr. Shuren") replaced Dr. Schultz as the Director of the CDRH. At all relevant times, Ulatowski was responsible for the management of approximately 200 FDA employees, including compliance officers, scientists, engineers, administrative personnel, and physicians. Ulatowski described the role of the Office of Compliance in the CDRH as ensuring that companies comply with federal rules and regulations – specifically the Code of Federal Regulations Quality Systems Regulation – concerning the design and manufacture of medical devices and to initiate actions, on behalf of the FDA, against companies that failed to meet applicable federal laws and regulations.

50. According to the FDA, the mission of the Office of Compliance in the CDRH is to promote and protect the health of the public by ensuring the safety and effectiveness of medical devices, the safety of radiological products, and enforcing the Federal Food, Drug, and Cosmetic Act and implementing regulations. As the Office of Compliance states on its website, "We proactively engage the regulated industry and the research community through many avenues of education and

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regarding the Company's Colleague remediation efforts omitted substantial facts and information. The effect of these misrepresentations and minimizations was to misrepresent to the public the Company's true financial circumstances.

[3] The FDA's CDRH is responsible for regulating firms that manufacture, repackage, relabel, and/or import medical devices sold in the United States. In addition, CDRH regulates radiation-emitting electronic products (medical and non-medical) such as lasers, x-ray systems, ultrasound equipment, microwave ovens and color televisions.

public interaction to foster understanding of relevant laws and regulations to promote and maximize voluntary compliance."

51. Ulatowski stated that actions by the Office of Compliance are based, in part, on the outcomes of inspections of manufacturing facilities. When the CDRH Office of Compliance initiates an action based on an inspection, there are three possible actions the office can take: (1) no action; (2) voluntary action by the company (requested in writing by the Office of Compliance); or (3) official action, which includes an official notification (a warning letter) highlighting deficiencies observed during an inspection and requiring that the manufacturer correct those deficiencies.

52. Following the issuance of a warning letter, the Office of Compliance re-inspects to determine if the problems noted in the warning letter have been corrected. If the company is still not in compliance on the follow-up inspection, the Office of Compliance takes the next step, which involves seizures, injunctions and/or civil monetary penalties against the offending company. In those instances, the Office of the Chief Counsel in the CDRH drafts a complaint for any such action and the cases are brought before the appropriate court by the Department of Justice. During the injunctive process, there are two possible outcomes – either the case may go to court or the FDA and the company will enter into a consent decree. In Baxter's case, it entered into the Consent Decree with the FDA regarding the Colleague and the Company's quality systems in 2006.

53. Plaintiff also consulted with Betty Collins ("Collins"), who worked for the FDA for more than 30 years in several positions until she retired in May 2010.[4] For approximately the last 12

[4] Attached hereto as ***Exhibit "B"*** is a true and correct copy of the Declaration of Betty Collins in Support of Lead Plaintiff's Amended Consolidated Class Action Complaint for Violation of the Federal Securities Laws (the "Collins Declaration"). As set forth in the Collins Declaration and herein, Baxter and its high-ranking representatives, including Parkinson, had actual knowledge of the Company's inability to comply with the terms and conditions of the Consent Decree, and that Defendants' Class Period statements regarding the Company's Colleague remediation efforts omitted substantial facts and information. The effect of these

years of her employment with the FDA, Collins worked as the Director, Division of Enforcement A in the Office of Compliance in the CDRH. In her capacity as the Director, Division of Enforcement A, Collins directly reported to Ulatowski, and ultimately to Dr. Schultz and later Dr. Shuren. As the Director, Division of Enforcement A, Collins was responsible for all compliance issues within the CDRH, including sending warning letters and overseeing enforcement actions. As a result, Collins was directly responsible for overseeing the FDA's implementation of the Consent Decree as well as all of Baxter's remediation efforts for the Colleague, including evaluation of Baxter's quality control systems.

54. Both Ulatowski and Collins have first-hand, personal knowledge concerning Baxter's interactions with the FDA and the CDRH regarding the Colleague infusion pump. As set forth below, it was absolutely clear to Defendants throughout the entirety of the Class Period that Baxter was not meeting its obligations for remediating the Colleague. In that regard, the FDA and its officials repeatedly told Baxter representatives, including Parkinson, that the Company's Colleague remediation efforts were unacceptable, that fixes proposed by the Company were mere "Band-Aids" that simply caused more problems and required additional Class I recalls, and that the Company demonstrated nothing short of "absolute incompetence" in its remediation efforts for the Colleague pump.

VIII. SUBSTANTIVE ALLEGATIONS

A. The Company and Its Business

55. Baxter is a global, diversified healthcare company that develops, manufactures, and markets a variety of healthcare products used by hospitals, clinics, dialysis centers, nursing homes,

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misrepresentations and minimizations was to misrepresent to the public the Company's true financial circumstances.

rehabilitation centers, doctors' offices, clinical and medical research laboratories, and patients in their homes.

56. Baxter's operations are made up of three segments: BioScience; Medication Delivery; and Renal. The BioScience segment produces or processes recombinant and plasma-based proteins to treat hemophilia and other bleeding disorders, plasma-based therapies to treat immune deficiencies and other chronic and acute blood-related conditions, products for regenerative medicine, and vaccines.[5] In 2009, Baxter's BioScience business generated $5.6 billion in sales, approximately 45% of the Company's total sales.

57. Among other things, the Company's Medication Delivery business manufactures intravenous ("IV") solutions and administration sets, as well as infusion pumps. The Company's Renal business, which is not at issue here, provides products to treat end-stage renal disease, or irreversible kidney failure. The Company has its own sales force and also makes sales to and through independent distributors, drug wholesalers acting as sales agents and specialty pharmacy or homecare companies. In the United States, Cardinal Health, Inc. ("Cardinal Health") warehouses and ships a significant portion of the Company's products through its distribution centers. In 2009, the Medication Delivery business generated $4.65 billion in sales, approximately 37% of the Company's total sales.

[5] Recombinant is a medical term that means a new entity resulting from genetic recombination. Thus, recombinant plasma is man-made and can be used for preventing and controlling bleeding in patients with hemophilia. The Company sells its recombinant factor VIII therapy under the name Advate, which is produced with no blood-based additives to eliminate the potential risk of infectious agents that may be present in such additives.

B. The Company's Long and Tortured History with the Colleague Infusion Pump Leads Defendants to Mislead the Market

58. As set forth above, Baxter's Medication Delivery segment manufactures and sells products that deliver intravenous fluids such as medication or nutrients to patients in a controlled manner. These include IV solutions and administration sets, premixed drugs and drug-reconstitution systems, pre-filled vials and syringes for injectable drugs, infusion pumps, and inhaled anesthetics, as well as products and services related to drug formulation and enhanced packaging technologies. Global Infusion Systems is the division within the Company's Medication Delivery segment responsible for the Company's infusion pumps.

59. One of Baxter's Medication Delivery products was the Colleague infusion pump, a medical device that delivers IV fluids and medicine to patients in hospitals, outpatient surgical centers, clinics, nursing homes, and in ambulances. The Colleague family of devices were available as a triple channel and a single channel volumetric pump. The models included Mono, CX, and CXE. The Colleague was intended to be used throughout the hospital, including, for example, in the emergency department, intensive care units, surgical suites, labor and delivery, as well as adult and pediatric wards.

60. Baxter began selling its Colleague pump in the United States in 1997, and it became a market-leading infusion pump, with more than 205,000 units sold domestically. Given numerous design, user interface, and battery deficiencies, however, the Colleague pump came under FDA scrutiny beginning in 1999. Since that time, the Colleague pump has been the subject of at least seven Class 1 recalls for battery failure, inadvertent powering off, data service errors, and software issues, among other serious problems. A Class I recall is the most serious type of recall and involves situations in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death in patients undergoing treatment with the product.

61. For example, in 2005, Baxter notified customers about ongoing issues with the Colleague that were associated with eight patient deaths and a number of serious injuries. Four of the Company's "customer letters" were classified as Class I recalls by the FDA. Given the gravity of the Colleague's problems, the FDA conducted various inspections of Baxter facilities and raised concerns about not only the design of the Colleague pumps, but also Baxter's enterprise-wide internal quality systems, as well as product surveillance and corrective and preventative actions.

62. Then, in June 2005, the Company stopped all United States sales and shipments of its Colleague infusion pumps. As announced in a press release by Baxter in September 2005, Baxter had received a letter from the FDA in February 2005 due to reports of damage to the Colleague pump batteries including swelling and excessive discharge, which could render the pump incapable of operating on battery power. In response, Baxter agreed to voluntarily hold all future shipments of the Colleague pump and to continue to address this issue through remediation efforts.

63. Despite Baxter's so-called remediation efforts, on October 12, 2005, the United States filed a complaint in this Court to effect the seizure of Colleague (and SYNDEO) infusion pumps that were on hold in Northern Illinois. The complaint alleged, among other things, that the Colleague pumps were adulterated and misbranded under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§351(c), 351(h), and 352(t)(2). Following the filing of the seizure litigation, United States Marshals in the Northern District of Illinois seized more than 6,000 Colleague pumps on October 12, 2005, at Baxter's facilities, as well as at Cardinal Health's facilities, and again on October 27, 2005 at a Baxter facility. The seizure litigation alleged the Colleague pumps were: (i) adulterated because their quality fell below that which they purported and were represented to possess; (ii) adulterated because the methods used in, and the facilities and controls used for, their manufacture, packing, storage, and installation were not in conformity with good manufacturing practices and therefore

were inadequate quality systems that failed to meet applicable regulations; and (iii) misbranded because Baxter failed or refused to furnish statutorily required information.

64. On June 29, 2006, following a number of Class I recalls relating to the performance of the pumps, as well as the seizure litigation, Baxter, Parkinson, and Arduini (the Company's then-Vice President and President of Baxter's Medication Delivery Services) entered into a Consent Decree for Condemnation and Permanent Injunction with the United States. Among other things, the Consent Decree permanently enjoined Baxter and Parkinson from "manufacturing, processing, packing, repacking, labeling, distributing, or importing into the United States any model or components" for its Colleague pumps in the United States. The Company was also required to stop manufacturing or distributing any infusion pumps that had certain components or devices in common with the Colleague pump, including its software systems, computer motherboards, processors, sensors, timing circuitry, power systems and pumping mechanisms. The Consent Decree required Baxter and Parkinson to provide the FDA with written notice as to how the Company would remediate the Colleague pumps, and mandated that Baxter could not begin any remediation efforts without the FDA's prior written authorization.

65. The Consent Decree also covered Company processes and procedures the FDA found to be lax or inadequate and thus resulted in faulty Colleague pumps. For example, the FDA faulted the overall quality systems and procedures at Baxter, including the procedures for manufacturing, processing, packing, repacking, labeling, holding and distributing infusion pumps as well as processes for determining whether Baxter's facilities and controls were operated and administered in accordance with FDA regulations.

66. Therefore, Baxter was required to retain an independent expert to conduct inspections at Baxter's facilities that manufacture, process, or distribute the Colleague, and to review and determine whether Baxter's methods, facilities, and controls were operated and administered in

conformity with FDA regulations. The Company was also required to report to the FDA in writing "Baxter's current state of compliance" with respect to good manufacturing practices and quality systems regulation. On top of the foregoing, the Company was also required to retain independent auditors to inspect the operations at Baxter's infusion pump facilities at varying intervals for at least a total of four years. Following their inspections, the auditors were required to prepare written audit reports expressing in detail an opinion as to whether Baxter was in compliance with the FDA's regulations and the Consent Decree. The auditors were required to "assess the adequacy of corrective actions taken by Defendants to correct" all audit report observations. The Company was also required to "maintain the complete Audit Reports and all of their underlying data in separate files at their facilities" and to promptly make them available to the FDA upon request. To the extent any audit report contained adverse observations, Baxter and Parkinson were required to correct those observations within 35 days – or seek additional time from the FDA.

67. Finally, the Consent Decree required Baxter and Parkinson to submit a detailed "Corrective Action Plan" or "CAP" to bring the Company's Colleague infusion pumps currently "in use in the United States by physicians, hospitals, pharmacies, and other users/facilities into compliance with" FDA regulations. The Consent Decree stated that if at any time after its entry, the FDA determined that Baxter failed to comply with any provision of the Consent Decree, or violated any portion of the FDA's regulations, that the FDA could order any additional corrective actions necessary to achieve compliance, including a complete recall of the Colleague pumps. Therefore, the Consent Decree also outlined the steps Baxter was required to take in order to resume sales in the United States, which included obtaining FDA approval for the Company's remediation plan to correct deficiencies of the Colleague pumps still in operation, as well as submitting to third-party expert reviews of Colleague operations.

68. At bottom, the Consent Decree subjected the Company – and Parkinson individually – to substantial reporting requirements with the FDA. Parkinson, as a party enjoined by the United States, thus was required by the Consent Decree to have extensive knowledge concerning and direct involvement with the Company's Colleague remediation efforts, communications with the FDA regarding such efforts, and the risks to the Company stemming from any failure to comply with the Consent Decree. At all times, including throughout the Class Period, Parkinson was intimately familiar with all aspects of the Colleague pump, Baxter's remediation efforts, and the Company's communications with the FDA.

69. As set forth above, although the Consent Decree mandated that Baxter stop selling new Colleague pumps, approximately 205,000 of the pumps remained on the market in the United States and were still in use at hospitals and other healthcare facilities at the start of the Class Period. Describing why the Colleague remained on the market, Ulatowski stated the FDA was concerned that removing all of the Colleague pumps from the U.S. healthcare system at one time would create a shortage of infusion pumps that could not be immediately corrected and would lead to even more detrimental outcomes in patient care. This concern existed even though the Colleague's numerous deficiencies and heath threats were "intolerable," causing an unacceptable rate of death and serious injuries in patients treated with the Colleague pump. At the time of the Consent Decree, the FDA conducted a shortage assessment to determine the impact removing the Colleague pump from the healthcare system would have on patient care. Thus, the Consent Decree served as the framework for the FDA's expectations with regard to remediation of the Colleague pump.

70. In that regard, during 2007, Baxter and the FDA engaged in discussions for Baxter to establish a CAP with a timeline to remediate the Colleague and ensure the supply of safe infusion pumps to users of the medical device and the healthcare industry in general. These conversations

involved representatives from Baxter, including Parkinson. As part of this process, the FDA made requests to Baxter to make certain corrective actions to remediate the Colleague.

71. In order to comply with the Consent Decree, Baxter's remediation plan for the Colleague pump was threefold: (1) remediate the single channel versions of the Colleague; (2) remediate the triple channel Colleague pumps; and (3) gain FDA approval for an entirely new Colleague infusion pump. As set forth below, the Company failed to successfully satisfy elements of its remediation plan. To the extent Baxter secured FDA approval for the Company's plan to remediate the single channel pump, Baxter was unable remediate in a timely manner the single channel pumps that were still in use. Indeed, there were a large number of Colleague pumps that had not been remediated in 2009 (any the Company's "fixes" resulted in additional recalls). To the extent Baxter sought to remediate the triple channel pump, Baxter's proposed plans never received FDA approval. Finally, Baxter never even got to the point of proposing any acceptable plans for a new Colleague infusion pump. As a result of continuing ongoing discussions with the FDA, the extensive problems with all three prongs of Baxter's remediation efforts were known at all times to Defendants throughout the entirety of the Class Period, and are set forth in detail below.

72. Before Baxter could either remediate the Colleague or bring a new Colleague pump to market, the Company was required to get FDA "510(k)" clearance. According to the FDA, §510(k) of the Food, Drug and Cosmetic Act requires device manufacturers who must register to notify the FDA of their intent to market a medical device at least 90 days in advance. This is known as Premarket Notification – commonly referred to within the industry as a "510(k)." This 90-day notification allows the FDA to determine whether the device is substantially equivalent to a device already placed into one of the three classification categories, *i.e.*, whether the device is as safe and effective as similar, legally marketed products. Specifically, medical device manufacturers are required to submit a 510(k) if they intend to introduce a device into commercial distribution for the

first time or reintroduce a device that will be significantly changed or modified to the extent that its safety or effectiveness could be affected. Such change or modification could relate to the design, material, chemical composition, energy source, manufacturing process, or intended use.[6]

73. As a result of numerous Class I recalls and the FDA-issued Consent Decree for the Colleague, as well as the Company's quality controls, Baxter was required to present to and receive approval from the FDA for a new 510(k) submission. The FDA had identified a number of defects with the Colleague pump, and as a result, Baxter and the FDA's Office of Device Evaluation ("ODE") had frequent contact in the form of meetings in 2006 and 2007 regarding the problems Baxter needed to fix with a Colleague. Within the FDA, ODE is responsible for clearing 510(k) submissions. Generally describing the Company's failing remediation efforts for the Colleague infusion pumps, Ulatowski and Collins recalled that Baxter presented, for example, a fix for the Colleague's software, the FDA looked at it, ODE cleared it, and after having the device back on the market for a few months with the supposed "fix," the Colleague pump was recalled again. Due to the number of problems with the Colleague pumps and the number of problems that resulted from Baxter's "fixes" submitted during the 2006 and 2007 timeframe, any changes Baxter submitted were scrutinized more closely. As a result, there were numerous meetings between the FDA and Baxter both leading up to and during the Class Period.

1. During August 2007, with Problems Across the Board, the FDA Tells Baxter Representatives that the Company is Wholly Understaffed to Remediate the Colleague

74. On August 22, 2007, the FDA met with Baxter at the FDA's facilities in Rockville, Maryland regarding Colleague remediation. Along with Parkinson, White, Baxter's Vice President

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[6] *See* http://www.fda.gov/medicaldevices/productsandmedicalprocedures/deviceapprovalsandclearances/510kclearances/default.htm (last visited Apr. 11, 2011).

of Quality Operations, Arduini, Baxter's President of Medication Delivery, and Ed Basile ("Basile"), Baxter's attorney, attended the meeting on behalf of Baxter. Representatives from the FDA included Ulatowski and Collins, as well as Dr. Schultz, Mark Raza ("Raza"), and Michelle Svonkin ("Svonkin") (Raza and Svonkin are FDA attorneys). Ulatowski recalled that it was apparent to FDA officials during this meeting that if it was going to comply with the terms of the Consent Decree, the Company would need to apply considerably more resources to make the necessary fixes to the Colleague pump. Ulatowski stated that based on what Parkinson told the FDA, the Company was "wholly understaffed" to comply with the Consent Decree and was "incapable of remediation" with regard to the Colleague pump. Ulatowski recalls telling Parkinson that Baxter was not adequately staffed to remediate the problems of the Colleague pump, stating directly to Parkinson that although the Company had 1,000 salesmen, it only had "Manny, Mo, Jack, and the janitor" working on remediation efforts.

75. Ulatowski recalled from the Company's initial meetings with the FDA that from the onset of the Consent Decree, Baxter had problems "across the board" requiring a host of corrective actions. The Colleague pump was an "old platform," and due to the aging design, the fixes proposed by Baxter were only "Band-Aids." The Company was "just patching one thing after another." Ulatowski described how when the Company would get one problem "fixed," a number of other problems would arise. He described that for almost all of the fixes put forward by the Company, after a few weeks or months the Company would ultimately have to recall the Colleague as a result of the fix. Ulatowski described the Company's efforts as demonstrating "absolute incompetence" and that regardless of the fixes proposed or undertaken, the Colleague pump always remained violative. In general terms, the Company was unable to "catch up" to the problems within the device and throughout the entirety of the Class Period, Baxter was never any closer to fully remediating the Colleague pump.

2. Baxter and the FDA Meet Again on November 25, 2008, with Similar Results, but This Time, the FDA Requires Clinical Data

76. Another meeting between Baxter and the FDA occurred on November 25, 2008, at the FDA's Rockville, Maryland offices. Parkinson, Arduini, White, and Basile attended on behalf of Baxter, while FDA representatives included Dr. Schultz, Ulatowski, Donna Tilman ("Tilman"), Director of the FDA's Office of Device Evaluation, Anthony Watson (" Watson"), the FDA Branch Chief in the Office of Device Evaluation, Scott MacIniyre, Director of the FDA's Chicago District Office, as well as other FDA staffers. The issues discussed during the meeting revolved around the Consent Decree and, during the meeting, the Baxter representatives updated the FDA as to where the Company stood with its remediation efforts.

77. During the meeting, White presented a timeline for a new infusion pump and a remediation plan for the Colleague pump. Ulatowski described how the timeline demonstrated Baxter would not be able to bring a new pump to market until 2014 or 2015. Ulatowski described Baxter's timeline as "unsatisfactory" and stated that the FDA consistently told Baxter – at this meeting and throughout the Class Period – to shorten its timelines by all means possible. Put simply, throughout the entirety of the Class Period, Ulatowski and the FDA made it crystal clear to Baxter and Parkinson that Baxter's proposed remediation timeline was always "unsatisfactory."

78. The November 25, 2008 meeting between Baxter and the FDA was indeed pivotal because it was the first time that Dr. Schultz informed Baxter that the Company would be required to submit ***clinical data*** to supplement the Company's future 510(k) filings for both remediation on the triple-channel Colleague pump as well as proposals for a new Colleague device. Ulatowski recalled that Baxter and its representatives strenuously argued that simulated data, rather than clinical data, would be sufficient for the Company's Colleague-related 510(k) submissions, but that the FDA would not relent on this point. Collins recalled that requiring clinical data to support a 510(k)

submission is an unusual requirement. 510(k)s always contain descriptive information and usually contain performance data, such as ***non-clinical*** test data, to support evidence of "substantial equivalence." The FDA required Baxter to submit clinical data to support future Colleague 510(k) submissions because soon after the Company's prior Colleague 510(k) submission, which was cleared by the FDA, Baxter was forced to institute another recall on the Colleague pump.

79. Describing the FDA's position at the time, Ulatowski recalled that because of the recalls associated with previous Colleague "fixes," Dr. Schultz demanded clinical data demonstrating that the changes to the Colleague were safe and effective. Collins confirmed that in 2008 the FDA determined Baxter would have to provide clinical data to support future 510(k) submissions. Collins also stated that the decision to require clinical testing to support future 510(k) submissions was repeatedly told to Baxter. As a result, Baxter would be required to show the FDA "beyond a shadow of a doubt" that it had fixed all of the Colleague's problems. By this time, as a result of the Company's history of failed remediation attempts, the FDA simply did not trust Baxter to actually fix the pumps, viewed the Company as incompetent, and also viewed the fact that more than 200,000 defective Colleague pumps were in the market as "intolerable" and as a situation that "could not be sustained." Ulatowski stated the FDA simply had "no faith" in Baxter's ability to adequately simulate clinical use and, therefore, actual clinical data on the Colleague pump would be required going forward.

80. Ulatowski explained generally that it could take a Company six to nine months to assemble and provide simulated data necessary to accompany a 510(k) submission. Without compliance with 21 C.F.R. Part 820, the Quality System Regulation ("Part 820"), Baxter lacked the necessary quality systems to even undertake clinical trials that would produce the credible clinical data now required by the FDA. In other words, the lack of Part 820 compliance undermined the

FDA's confidence in the Company's processes for collection, verification, and validation of data that would be submitted in a 510(k).

81. As a result, Defendants knew it would take the Company at least a couple of years to generate the clinical data required for a 510(k) submission. Therefore, if Baxter submitted a 510(k) to the FDA, it would have been rejected both because Baxter had no clinical data to support the submission and, even if the Company did have the data, its credibility was undermined by Baxter's ongoing failure to comply with Part 820 (which was required by the terms of the Consent Decree). Thus, by at least November 25, 2008, Baxter, Parkinson, and high-ranking Company employees knew unequivocally that the FDA required clinical data on the Colleague pump that would take years to complete. Without clinical data demonstrating that Baxter had successfully remediated the triple channel Colleague pump as well as successfully designed a new Colleague pump, Baxter was "dead in the water" and could not comply with the Consent Decree. Despite their crystal-clear understanding of the FDA's clinical data requirement, the FDA's repeated, bluntly-expressed displeasure with Baxter's incompetence, and the FDA's flat-out rejection of Baxter's proposed remediation timeline, Defendants conveyed none of this information to the market prior to or during the Class Period.

82. Explaining why the FDA did not simply recall all defective Colleague pumps that were in the market, Ulatowski stated the FDA was concerned with patient care. With more than 200,000 Colleague pumps still in use in the U.S. healthcare system, the FDA had to make sure other manufacturers had the capacity and ability to replace the Colleague pumps. In that regard, the FDA told Baxter representatives that the Company should explore alternative pumps to replace the Colleague. Ulatowski and Collins recalled that following the FDA's suggestion that Baxter explore alternative pump manufacturers for Colleague replacements, Baxter entered into an agreement with

Sigma International General Medical Apparatus, LLC ("Sigma") to become the exclusive distributor of all Sigma infusion pumps.

3. In January 2009, Baxter Issued Yet Another Class I Recall for the Colleague

83. Thereafter, in January 2009, Baxter prepared an urgent device correction notice for the Colleague single and triple channel pumps that addressed hazards associated with improper cleaning, failure codes, and defective batteries. The FDA reviewed, commented, and revised the draft recall notice which was ultimately issued on or about January 23, 2009. Baxter's correction notice was classified as yet another Class I recall.

84. In addition, during January 2009, Baxter submitted a CAP supplement that included the Company's proposed plans for remediation of the defective triple channel Colleague pumps. Collins recalled that the CAP supplement was inadequate as proposed in that a number of safety concerns were not addressed. Collins stated that, once again, the Company's submission did not address how the adulterated and misbranded pumps that remained in the U.S. healthcare system would be remediated.

85. In response, the FDA prepared and provided specific questions to Baxter regarding the remediation proposal. For example, the FDA requested a Health Risk Evaluation to help determine the risk to patients/users before considering Baxter's proposal. The FDA also requested specific medical device complaint data from the Company. Describing the specific questions to the CAP supplement, Collins stated that the FDA asked the Company to provide concrete data to support its proposal. The FDA told the Company, "if you [Baxter] give us [the FDA] a proposal, we need to see data to support it." Describing the Health Risk Evaluation, Collins stated the FDA wanted to determine if the Company had considered the overall health risk posed by the Colleague, as presented in the CAP supplement. In other words, to determine whether Baxter's proposal created a greater health risk, the FDA provided the Company with specific questions. Because the FDA had

not previously asked Baxter for a Health Risk Evaluation, Collins characterized the FDA's request in January 2009 as an "escalation" of the requirements placed on the Company. Collins further recalled that in November 2008, the FDA gave Baxter a "heads-up" that the FDA would be asking for the Health Risk Evaluation. In January 2009, the FDA made it official through a formal request.

86. Summarizing the questions posed in a generic Health Risk Evaluation, Collins stated that a risk evaluation routinely includes questions such as: Have you identified the problem? What is the number of defects; What is the number of malfunctions? What is the number of serious injuries? What is the number of deaths? What is the population at risk? and What is the frequency of the defect? Collins stated that Baxter's response to the Health Risk Evaluation would be based on complaints the Company received from customers and from medical device reports. The Company could also review the results of its finished product testing of remediated devices to determine if they were meeting product specifications, particularly in light of the Company's quality audits.

4. In February 2009, Baxter Attempts to Respond to FDA Questions and Concerns – the FDA's Tolerance for Baxter is Exhausted

87. The FDA and Baxter met again on February 24, 2009, at the FDA's Rockville, Maryland offices. FDA representatives included Ulatowski, Collins, Valerie Flournoy, the FDA's Chief of the General Hospital Devices branch, as well as other FDA staffers. On Baxter's behalf, the meeting was attended by White, Arduini, Kevin McCulloch ("McCulloch"), Baxter's General Manager of Global Infusion Systems, Ross Krogh, Vice President of Research and Development in Engineering, and Neil Pankau, Director of Baxter's Consent Decree Office, Global Infusion Systems. This meeting was held so that Baxter could provide responses to the FDA's questions and concerns for Baxter's Colleague remediation efforts. During the February 24, 2009 meeting, the FDA listened to Baxter's presentation and shared the FDA's concerns and comments. Collins

explained that this was Baxter's opportunity to tell the FDA why its current proposal for remediating the defective Colleague devices was any different than its past proposals.

88. Ulatowski recalled that by early 2009, the FDA's "tolerance was exhausted." In that regard, Ulatowski recalls making a presentation to Dr. Shuren, the FDA's deputy commissioner, and others about ongoing compliance issues. During the presentation, FDA representatives talked specifically about Baxter pumps, the Consent Decree, and the Company's many problems. Dr. Shuren expressed no tolerance for Baxter and its predicament, and clearly stated the FDA would "move quickly" on Baxter. During this and other meetings, FDA participants discussed the fact that the Baxter timeline for complying with the Consent Decree was not satisfactory. Ulatowski stated that the FDA was "unsatisfied" with Baxter's timeline and that this message was conveyed to Baxter in writing, on calls, and every time the FDA met with the Company and its representatives. In no uncertain terms, Baxter, Parkinson, and others were told to expedite Baxter's corrective actions, that Baxter had to complete its remediation efforts much more quickly, and that the Company had to remedy its enterprise-wide quality control deficiencies.

5. Between March and May 2009, Baxter Moves No Closer to Remediating the Colleague and the Company's Quality Systems Failures Continue Raising Red Flags

89. During March 2009, Baxter provided the FDA with the above-mentioned Health Risk Evaluation. By this time, the Company had an authorized, *i.e.*, FDA-cleared, 510(k) to remediate the single channel pump, but had not yet received authorization for remediation of the triple channel Colleague pump. But during March 2009, the FDA informed Baxter that its CAP supplement was unauthorized. In other words, Baxter's proposal for remediating the triple channel Colleague pump was rejected. Baxter was told by the FDA, via a letter, to withdraw the CAP supplement and submit another one that included a timeline for complying with all conditions of the Consent Decree and to perform a comprehensive Health Risk Evaluation for all Colleague populations. According to

Collins, the Company's CAP supplement did not provide data to support its proposal. In addition, Collins noted that the March 2009 request by the FDA for a timeline for how Baxter proposed to remediate the triple channel pump was "an additional escalation." In other words, this action by the FDA was a clear indication to Baxter that the Colleague issues had grown even worse.

90. Between April and May 2009, the FDA's concerns about Baxter's ability to remediate the Colleague pump continued to worsen. The FDA was well aware of the public health risk associated with the Colleague pumps, and on the heels of the FDA's rejection of Baxter's CAP supplement (Baxter's remediation proposal), the FDA provided written questions to Baxter regarding its remediation efforts. According to Collins, the FDA wanted to know what impediments were causing the ongoing delays in fixing un-remediated single channel Colleague pumps. Other FDA questions focused on Baxter's timeline for achieving conformity with Part 820 for any outstanding issues that needed to be corrected with the Company's overall quality systems. The FDA also requested Baxter to provide an updated notification to its customers and users because the FDA felt that Baxter customers who had been waiting for some time on upgrades to their single and triple channel Colleague pumps, or a new replacement pump, needed to know the status of Baxter's remediation efforts and should be provided an update on the status of Baxter's CAP and submission of a viable 510(k).

6. Throughout the Class Period, Baxter's Colleague Pumps Remained Beset by a Host of Dangerous and Deadly Problems

91. Corroborating the accounts of Ulatowski and Collins, several Confidential Witnesses detailed the many problems plaguing the Company's Colleague pumps. One of the most serious was related to the battery. The Colleague is used as a plug-in device and has a battery backup, comprised of two lead-acid batteries. When the charge on the pump's batteries battery got low, the batteries could leak onto lead plates within the pump head and skew the machine's battery-life estimates. For example, the pump could display a message indicating three hours of battery life left when, in

actuality, there were only a few minutes left. The result of the batteries leaking and causing internal damage to the device was that the Colleague could shut down without warning, causing serious injuries to patients. CW 6 stated that the battery discharge was a "fundamental" flaw in the Colleague's design. Likewise, CW 3 recalled that the Colleague pumps would "just shut down" as a result of battery failures. Moreover, when the pumps did shut down, there was no alarm to alert nurses or staff. CW 6 recalled that the problems with the battery on the Colleague pump were so severe that when CW 6 was hospitalized, CW 6 told the doctors and nurses that CW 6 would not answer any questions until they assured her/him the Colleague pump was plugged into a wall outlet and not operating from its battery.

92. In addition to its severe battery flaws, the Colleague pump also had significant problems with its gaskets. According to CW 6, there were a number of incidents in which fluid would leak into the pump head because the seal on the gasket was flawed. This caused a build-up of moisture and humidity within the Colleague pump head that could, and did, lead to fires, in some instances. Summing up the extent of the Colleague's problems, CW 3 stated that Baxter had a "tremendous" number of pumps with a "long service history." Ulatowski and Collins independently confirmed the Colleague was beset by numerous significant and potentially life threatening problems, including battery and display failures, as well as diagnostic, software, and interruption of therapy problems.

93. As set forth herein, the Company was ill-prepared to extricate itself from the strictures of the Consent Decree. Problems with the Colleague persisted for years and the Company, despite its statements to the market, lacked the ability to remediate them. For example, on January 23, 2009, Baxter sent an "Urgent Device Correction letter" to customers regarding Colleague pumps in the United States, which notified customers about failure codes in Colleague pumps that caused them to "alarm" and stop infusing while delivering critical medication and fluids to patients. The

letter also included information warning of the possibility of the devices overheating, resulting in smoke and fire, if improperly cleaned and/or if there was compromised battery harness insulation. Additionally, Baxter notified customers about a high occurrence of damaged battery messages related to the use of the pump as a battery-operated device. The letter also stated there were serious injuries and/or deaths associated with failures the Company identified, and that for several of the adverse events, there was no way for users to prevent them from occurring. Then, on March 11, 2009, Baxter announced that the FDA had classified the Company's January 23, 2009 Urgent Device Correction letter to customers regarding Colleague pumps in the United States as yet another Class I recall.

a. The Company Lacked the Adequate Internal Controls and Processes Necessary to Successfully Remediate the Colleague Pump

94. Throughout the Class Period, Defendants assured the market that Baxter was committed to remediating the Colleague and that it was working to "get that resolved certainly in 2010." Defendants' external rhetoric was designed to and did mask a far different story and most certainly contradicted the Company's internal dialogue. Contrary to their statements to the market, Defendants knew or recklessly disregarded that Baxter was incapable of remediating the numerous problems plaguing its Colleague pumps for several known reasons, including internal quality deficiencies.

95. On top of physical problems with the Colleague, the Consent Decree highlighted internal quality control problems at Baxter. CW 1 recalled that the Consent Decree faulted the overall quality systems at Baxter, not only for the Colleague pumps but throughout the organization. Although the Company initially attempted to overhaul its entire quality organization after the Consent Decree was put into place, CW 1 stated that the Company realized its efforts were too large in scope. Instead, the Company – despite what the Consent Decree said – focused its quality

improvement efforts on overhauling the quality organization as it related to the Colleague line only. Echoing a theme shared by many former employees, CW 1 recalled that the Company's remediation efforts related to the Consent Decree suffered and languished because Baxter simply did not put enough resources into the effort. For example, rather than bringing in outside consultants to manage all remediation efforts required to get the Consent Decree lifted – as most companies in a similar position do – Baxter did not; rather, it assigned remediation efforts to employees already tasked with other jobs. The result was that it was difficult to make progress not only on regular tasks, but also on the remediation efforts. CW 1 recalled that employees were stretched too thin and were burning out from the excessive workload.

96. One glaring problem that prevented Baxter from being able to successfully remediate its Colleague pumps was that Baxter lacked any semblance of "design traceability" on its Colleague line, as well as other devices created by the Company. Put simply, the Company lacked adequate internal quality systems and was unable to properly trace the design evolution of the Colleague pumps and therefore had trouble going back to isolate the underlying causes of the problems that resulted with the pumps when they were in use. The Company's design traceability woes were exacerbated because the Colleague was not originally designed by Baxter, but instead was acquired by Baxter from another company. CW 1 and CW 6 each confirmed that Baxter never had traceability of the Colleague pump design.

97. Baxter, despite its size and market share, was very much a paper-driven company that worked with archaic systems. Design changes and other information were documented on paper for many years instead of in a computer database or software application – there were no coordinated databases and software at Baxter.

98. CW 1 recalled that Baxter attempted to remedy this situation as early as 1999 by purchasing and implementing a new software system called "Team Center," which was supposed to

track and store all design changes to Baxter devices across the Company. But Global Infusion Systems – the Baxter division responsible for the Colleague – successfully resisted using Team Center and did not actually implement it at the same time as the rest of the Company. As late as 2007, the Team Center system was only partially integrated into Global Infusion Systems. In fact, as of December 2009, CW 1 recalled it had not yet been fully adopted within Global Infusion Systems, despite the fact that it was the department responsible for designing and remediating Colleague infusion pumps. Thus, Global Infusion Systems was effectively "very siloed" from the rest of the Company and, according to CW 1, Baxter simply had no hope of the FDA lifting the Consent Decree under such circumstances.

99. Expanding on the Company's design traceability woes, CW 1 recalled several instances in which the Company's engineers in Singapore made changes to the design of the Colleague pumps that did not go through a formal corporate change control process. Thus, as engineering changes were being made, they were not documented outside of Singapore, and were not necessarily communicated to the Company's U.S.-based engineers. By making alterations outside of documented change control processes, Baxter exacerbated its design traceability woes and knew that it had no hope of getting out from under the Consent Decree.

100. Regarding the Company's quality systems deficiencies, CW 1 also described how Baxter lacked a process for "periodic document review," including the review of updates and/or changes to FDA regulatory requirements. Nor was there an escalation process if the reviews scheduled to take place did not occur. For example, an employee might be tasked with monitoring changes to regulatory requirements, but there was no process in place for requiring documentation of the review and there was no escalation process in place if the person tasked with performing those reviews missed deadlines.

101. As required by the Consent Decree, Baxter hired third-party auditors to perform mock FDA audit inspections to help identify issues with the Colleague pump. Baxter first retained Parexel International ("Parexel") in 2006, and then replaced Parexel with QualityHub, Inc. ("QualityHub"). Collins recalled that Baxter submissions to the FDA that had been reviewed by Parexel highlighted several areas in Baxter's quality systems that the FDA had problems with. Collins stated that one of the reasons Baxter could not adequately remediate the Colleague pump was problems with verification and validation. For example, every time Baxter made a submission to the FDA, the FDA continued to identify new areas of concern. Thus, the Company was "not catching" the totality of the Colleague's problems. Even after switching consultants, QualityHub continued to find problems with Baxter's quality systems.

102. CW 1 recalled that QualityHub conducted an audit in November 2008, as well as an additional audit prior to December 2009. According to CW 6, the QualityHub representatives sat in one conference room called "tech one" at Baxter while a dozen or so Global Infusion Systems employees camped out in another conference room called "tech two."

103. As part of the auditing process, Baxter employees performed testing on the Colleague pumps and submitted the test results to the auditors. For example, Baxter's engineering and quality employees would perform tests on the Colleague's software to identify glitches. Test scripts were produced by Quality Center, a software application used by Baxter and many pharmaceutical/medical device manufacturers to store test data, and Baxter employees would then write reports related to the results for submission to the FDA. Thereafter, CW 2, the Software Analyst/Validation Analyst, reviewed "test scripts" and checked the data in the reports against the data stored in Quality Center to ensure they were accurate, logical, organized, and contained proper data for submission to the FDA auditors. The reports included a series of codes and showed whether or not a certain type of test failed so that CW 2 could tell when a software glitch was detected in a

Colleague pump. Then, engineers and employees at a higher level within the Quality department would determine whether the bug was minor and fixable or major in scope.

104. Typically, the Company's lab testers and engineers would test the Colleague pumps, identify issues or problems such as a software glitch, make the appropriate fix and then run the tests on the pumps again. This type of quality testing is referred to in the industry as "waterfall" or "cycle testing," and was designed to continue until the pumps passed the validation testing. CW 2 stated that the Company was attempting to simulate problems on these new and existing pumps for reports to the FDA.

105. Employees also designed and wrote tests which had not yet been conducted. CW 6 worked on requirements testing (coming up with tests based on how the device is supposed to operate) and would include tests for under-delivery of medication, over-delivery of medication, interruption of therapy and the potential hazards in each of these cases.

106. The tests were performed on Colleague pumps that were in stock, but that had not been used by customers, such as hospitals and clinics. These were pumps that were produced at the same time as the other Colleague pumps that were on the market in the United States, but they had not been sold because the 2005 FDA recall prohibited Baxter from selling any more Colleague pumps in the United States.

107. As noted above, test results were organized and presented to the FDA auditors. After each audit inspection, the auditors prepared a written report providing details with regard to whether Baxter was in compliance with FDA regulations and assessing the adequacy of the corrective actions taken by Baxter.

108. CW 1 confirmed that following each audit, the third-party auditor would submit its results to the FDA. CW 1 also described how, if and when the third-party auditor determined that Baxter had satisfied remediation efforts related to the Consent Decree, it would notify the FDA,

which would then schedule an official audit. In all the years since the issuance of the Consent Decree, Baxter, however, never got to that point because one of its auditors, *i.e.*, QualityHub, ***always*** found that the Company had adverse issues preventing compliance with the terms of the Consent Decree.

109. CW 1 stated that the external auditors ***always*** found corrective actions that needed to be performed and/or determined that, to the extent actions were carried out, they were inadequate. Specifically, the Consent Decree required audit inspections to identify the root causes for the failure of the Colleague pumps and evaluate whether Baxter implemented steps to correct the failures as well as to identify procedures for reporting adverse events, such as steps taken by management to ensure implementation of adequate and effective quality system procedures, personal training to perform product failure, and corrective action and assessment activities, among other procedures.

110. In addition, during April and May 2009, the FDA continued to question the Company's issues with its quality systems. In that regard, Collins confirmed that Baxter hired Quality Hub to replace Parexel and to look at Baxter's processes and procedures in order to conform with 21 C.F.R. Part 820, which covers "Quality System Regulation," as required under the Consent Decree. Baxter still had not reached compliance with Part 820. During this April and May 2009 timeframe, the FDA started asking Baxter when it would achieve Part 820 compliance. Collins stated that, because of the terms of the Consent Decree, the Company could not be in a position to provide the FDA with acceptable data (*i.e.*, verifiable and validated data) to support a 510(k) submission without also complying with Part 820 – Baxter had to satisfy both sides of the equation. Collins recalled that during this timeframe, Baxter was having problems with design control, verification, validation, and meeting finished product specifications. Summing up the situation, Collins stated that in order for Baxter to provide clinical data and achieve "substantial equivalence," the Company would need to be able to demonstrate that its manufacturing processes were in

compliance with the Quality System Regulation. Without Part 820 compliance, it was clear that Baxter was going to continue to have serious problems with the FDA. According to Collins, "meeting quality system requirements are critical."

111. Expanding on the situation, Collins recalled that when Baxter first hired Parexel, the Company was designated as being in conformance with Part 820, at which point the FDA went back and conducted an inspection. The FDA undertook this inspection of Baxter's quality system in April 2007 and determined that the Company was not, in reality, compliant with Part 820. Because the FDA seeks to conduct these inspections on two-year intervals and based on the FDA's findings in 2007, the FDA conducted another quality system inspection in April 2009 – specifically between April 2-22, 2009. The result of the inspection was that Baxter knew it had continuing quality problems and the Company knew it failed to take a number of actions necessary to correct and prevent re-occurrence of nonconforming products. Despite Defendants' ongoing knowledge that Baxter's numerous quality control deficiencies would prevent the Company from even being able to submit an acceptable 510(k) submission based upon credible data, Defendants revealed none of these facts to the market during the Class Period.

7. Baxter and the FDA Meet in June 2009 and Baxter's Remediation Timeline Grows Even Longer

112. On June 11, 2009, there was another meeting between the FDA and Baxter. The meeting afforded Baxter an opportunity to answer the written questions posed to Baxter by the FDA and to address questions regarding recent Medical Device Reports ("MDRs") involving remediated and non-remediated Colleague pumps that had been reported to the Company. For the FDA, Ulatowski, Collins, Jason Brookbank, a FDA Consumer Safety Officer, Flournoy, and other FDA staffers participated in the meeting. For Baxter, representatives included White, McCulloch, and Pankau, Baxter's Director of the Consent Decree Office, among others.

113. During the June 11, 2009 meeting, Baxter discussed its current remediation activities and the status of what needed to be accomplished. Baxter also indicated that it was expanding the scope of Colleague remediation, focusing its resources, and increasing the number of people to work on both pump remediation and quality systems remediation. Despite this, the timeline Baxter presented to the FDA had both remediation and deployment efforts for the new Colleague pushed further back. Baxter also explained to the FDA that it had become the exclusive distributor of Sigma infusion pumps. As the meeting went on, the FDA closely questioned Baxter regarding its proposed remediation timeline. Baxter was told that its proposed timeline was unacceptable because the deployment for the remediated Colleague was too far out. The FDA also told Baxter the remediation was taking too long and needed to be expedited – remediation and deployment needed to be much sooner. As Collins explained, Baxter's proposed timeline was "unacceptable," and the FDA would not be "waiting around for two years for [Baxter] to replace the pumps."

114. At the conclusion of the meeting, Baxter was told to come back to the FDA with a new timeline and a new CAP supplement. During the meeting, FDA representatives also advised Baxter that the FDA believed an updated advisory needed to be sent to Colleague users because clear instructions needed to be provided to users/patients so they would have a better understanding of all Colleague issues, allowing them to both develop and put in place the proper risk mitigation strategies and emergency plans related to Colleague use. Collins stated that the FDA believed an updated advisory was necessary as a direct response to Baxter's failure to remediate the single channel pump and Baxter's failure to have an acceptable timeline for submission of a 510(k) for the new pump. Describing the basis for the advisory letter, Collins stated that hospitals needed to be reminded of the numerous problems with the product and needed to have backup pumps available.

115. Following the meeting, in July 2009 Baxter prepared a "Colleague Customer Advisory," as requested by the FDA. In the advisory, Baxter told customers of updates regarding

Baxter's actions and timeframe, and included a reminder of the deficiencies in the Colleague, timing for remediation, future plans for addressing quality issues, and the Company's anticipated submission of a 510(k). The advisory indicated that Baxter anticipated having a 510(k) submission by mid-year 2010 that would address all field corrections the customers had previously been notified about through numerous recalls. Prior to the Colleague Customer Advisory being sent out, the FDA reviewed it and commented on it, and then had a discussion with Baxter to address the FDA's revisions and edits. Collins stated that the advisory was required by the FDA because Baxter's previous timeline for remediating the Colleague was unacceptable. Moreover, Collins stated Baxter would have to make a "huge effort" in order to submit a new 510(k) by mid-year 2010 because the Company remained non-compliant with Part 820.

8. Parkinson and Baxter Representatives Meet with the FDA in August 2009 – Baxter Remains Years Away from Compliance with the Consent Decree

116. On August 10, 2009, Baxter and the FDA met yet again, this time at the FDA's Silver Spring, Maryland, White Oak facility in building number 66. Attending the meeting on behalf of the FDA were Dr. Schultz, Ulatowski, Collins, Flournoy, Brookbank, Marc Caden from the FDA's Office of Chief Counsel, and other FDA staffers. On behalf of Baxter, the participants were Parkinson, Arduini, White, and Brown. Baxter knew going into the meeting that the FDA was not satisfied with Baxter's previous presentations regarding Colleague remediation. As a result, Baxter representatives opened the meeting by stating they would issue the advisory notice to customers as the FDA requested back in July 2009. Baxter also indicated it would expedite remediation and submit a new 510(k) by mid-year 2010.

117. Baxter representatives also presented a timeline that would expedite the remediation and removal of all Colleague pumps from the market. Although Baxter shortened the proposed timeline presented for implementing corrections and remediating pumps, the Company remained

years away from actually being in compliance with the terms of the Consent Decree. At this meeting, the FDA informed the Company that it needed to submit a new CAP supplement that included the Company's latest proposal. Baxter was also instructed to engage the FDA's ODE in dialogue regarding the forthcoming 510(k) submission and other studies. Collins described Baxter's presentation as one that was a way for the Company to "feel the FDA out." Baxter and its representatives knew the Company's June 2009 proposal was not acceptable. Regardless, at the time of the August 2009 meeting, the Company did not have a CAP supplement "in hand." Moreover the Company still had not demonstrated Part 820 compliance and was not in a position to propose – much less initiate – any clinical trials that would produce verifiable and validated data demonstrating the Colleague's safety and efficacy. Nevertheless, the Company submitted another proposed timeline that had shortened the timeframe to remediate the Colleague by approximately one year.

118. Collins described how the FDA explained to Baxter during the August 2009 meeting that the Company "needed to be talking to ODE, like yesterday" if the Company had any chance of meeting the mid-year 2010 510(k) submission deadline. The discussions with ODE were meant to describe to Baxter the kind of clinical data required to receive clearance of the 510(k). Despite what Ulatowski and Collins described as "protests" from the Company over the clinical data requirement, there was no doubt at this point in time that the FDA expected Baxter to conduct clinical trials and gather clinical data prior to greenlighting any Colleague remediation plan. Indeed, since mid-2009 the FDA told Baxter that its timeline was "unacceptable." Because of the requirement that the Company submit clinical data in support of future 510(k) submissions, Defendants knew they were not going to be in a position to begin remediating the Colleague for a period of many years. Despite this, Baxter maintained its position that it could generate an acceptable 510(k) by mid-2010.

9. Colleague Remediation Plans are Delayed Again During September 2009, and the FDA Sends Baxter a Warning Letter Because of the Company's Ongoing Quality Control Problems

119. During September 2009, Baxter indicated to ODE that the Company would be submitting its pre-Investigational Device Exemption ("pre-IDE") by the end of September 2009, which was a preliminary step in the required process for Baxter to conduct any clinical trials on the Colleague. A pre-IDE is a test run for an IDE. When a pre-IDE is submitted, the ODE provides preliminary comments. The next step is the formal IDE, which, when approved, permits the movement of the device for the purpose of conducting a clinical study. The "exemption" in an IDE is from adulteration and misbranding so that the product can be moved and clinically studied. A sponsoring company, such as Baxter, must demonstrate in the IDE that there is reason to believe that the risks to human subjects from the proposed investigation are outweighed by the anticipated benefits to subjects and the importance of the knowledge to be gained, that the investigation is scientifically sound, and that there is reason to believe that the device as proposed for use will be effective.

120. Later in the month, however, Baxter informed the FDA's ODE that the Company's pre-IDE submission would not be made on time. As detailed by Collins and Ulatowski, by this point in 2009, the FDA knew Baxter could not present a satisfactory 510(k) because of the clinical data requirement – without IDE authorization, Baxter could not move the Colleague pumps and start the required clinical trials. Ulatowski stated that Baxter, on top of not re-submitting a 510(k) because the Company never found successful fixes for the pump, did not submit the necessary, underlying IDE application. As Collins stated, Baxter "couldn't get ahead of the problems." Indeed, the Colleague's problems were so severe that the FDA had identified, at one point, at least 33 defects with the pumps. These defects included, as set forth above, buffer overflow problems, battery problems, software problems, and other failures with the units' communication modules.

121. Ulatowski and Collins stated that when Baxter remediated one defect, the Company's "fixes" would often introduce new problems. Ulatowski further explained that Baxter could only submit a 510(k) for what would be a completely remediated product – otherwise the FDA would not approve it – but Baxter "never got that far." Although the FDA repeatedly asked the Company for additional information on the remediation plans (as Collins put it, the FDA "wanted the information and we wanted it then"), Baxter was unable to provide the FDA with sufficient detail or an acceptable remediation timeline. Collins described the Company's message as "we're working on it." Defendants, however, knew this was unacceptable and would be significant to the market and Company shareholders, yet chose to omit this critical information from their Class Period statements.

122. Collins also confirmed that Baxter had ongoing issues with its "quality systems." She described how Baxter had "all sorts" of problems. Collins stated that without Part 820 compliance, which was required by the terms of the Consent Decree, it was certainly clear throughout September 2009 that Baxter would not be able to produce verifiable and validated clinical data that was necessary to meet any mid-2010 deadline for submission of a new 510(k). Despite this, Defendants did not disclose these critical facts to the market and instead misled investors into believing that the Company's Colleague remediation was "on track" to be completed in 2010.

10. Its Tolerance Exhausted, in October 2009, the FDA Undertook Steps to Eliminate the Risk Associated with the Colleague

123. By October 2009, it was clear that Baxter had failed to take the appropriate and timely corrective actions to remediate the violative Colleague pumps in use in the U.S. healthcare system, to submit an acceptable 510(k) application based on clinical data, or to improve Baxter's quality systems to a level that would comply with the terms and conditions of the Consent Decree. Specifically, although subject to the Consent Decree since 2006, Baxter failed to remediate a significant number of single channel Colleague pumps. Baxter also failed, since 2007, to correct the "buffer overflow" issue with its triple channel Colleague pump. As a result, a large number of un-

remediated triple channel pumps remained in the market. As set forth in the September 10, 2009 warning letter, Baxter also was continuing to produce violative inspections regarding continued deviations from the quality systems regulations. Despite the FDA's clear, consistent, and repeated instructions, Baxter submitted a pre-IDE package to the FDA's ODE requesting that clinical data not be included in the study, but that nonclinical, simulated data could be used instead. Put simply, Baxter did not submit the pre-IDE study with clinical data as requested by the FDA through the ODE. Defendants knew the Company's submission was grossly insufficient and would be rejected. It was at this time, because of Baxter's numerous, ongoing failures to remediate the Colleague, submit a plan for clinical data to the FDA, or remedy its host of quality control problems, that the FDA decided to initiate a "Triple R" remedy.

124. As the FDA weighed how to best deal with Baxter and the ongoing fiasco that was the Company's Colleague remediation efforts, Ulatowski and Collins, as well as FDA counsel, discussed instituting and using a remedy known as "Replacement, Repair, and Refund" or the "Triple R." By this time, the FDA's concerns about the Colleague pump had reached a crisis level – the FDA wanted the Colleague pumps out of the market and wanted Baxter to provide compensation to those individuals and institutions that had purchased Colleague pumps. The FDA's level of frustration with Baxter was very high. During this same time period, Baxter representatives were asking the FDA for approval to send out an "end of life" letter, meaning that the Colleague would no longer be in use by a certain date. Collins stated Baxter wanted to "draw a line in the sand" by which customers would have to secure new pumps. In this regard, White was contacting the FDA to determine whether Baxter had received approval to send an end-of-life notification out to Colleague users.

125. Collins stated that based on Baxter's history, there was a lack of confidence as to whether Baxter could "come in" with a satisfactory 510(k) submission because the Company simply

could not get ahead of all of its Colleague-related problems. Summing up Baxter's position, Collins stated the Company never advanced to the point where it could address all Colleague defects or internal quality shortcomings. Without being able to address all the defects, the FDA would not approve any remediation plan for the Colleague pump.

126. Describing the reasons behind the Triple R, Collins and Ulatowski stated that the FDA had talked to Baxter and learned there were triple channel infusion pumps in active use in the U.S. healthcare system that had yet to undergo substantial remediation, and learned additional information about the Company's proposed timeline for remediation, which remained unacceptable.

127. Ulatowski and Collins recalled that one of the reasons the FDA decided to use the Triple R remedy was that it was necessary to break Baxter's contractual agreements with its customers. For example, Baxter bundled long-term contracts for Colleague pumps with various other products, such as tubing and other accessories. As a result, hospitals were "boxed in" by these contracts. The Triple R effectively nullified those agreements between Baxter and its customers with regard to the Colleague pump and removed the pumps from the healthcare system completely.

128. As set forth above, during 2008 and 2009, Baxter and the FDA engaged in ongoing discussions wherein the FDA's Office of Compliance in the CDRH continuously communicated to Baxter, Parkinson, and other Company representatives that the Company's remediation plans were insufficient. Ulatowski and Collins both described how the dialogue between the Company and the Office of Compliance changed dramatically as the FDA began moving forward with the necessary steps to implement the Triple R. As Ulatowski characterized it, the Office of Compliance became "silent" with regard to the Colleague pump when contacted by Baxter. Likewise, Collins described how the FDA's Office of Compliance limited its discussions with Baxter about the Colleague pump and, instead, encouraged the Company to work with ODE. There was, without a doubt, a clear and

thus significant shift in the way the Office of Compliance communicated with Baxter regarding the Colleague pump.

129. For example, Ulatowski recalled that White and Basile continued to attempt to contact the Office of Compliance for further discussions during late 2009 and early 2010, but that the Office of Compliance stopped responding in any substantive manner and told Company representatives that the Office of Compliance could not provide any further information. Characterizing the silence, Ulatowski stated that the Office of Compliance's refusal to engage in substantive commentary would signal to an experienced manufacturer such as Baxter that the Office of Compliance was "considering an action." In other words, Baxter, Parkinson, and Company representatives would have clearly known that the Office of Compliance was evaluating and considering additional punitive actions, under the terms of the Consent Decree, regarding Baxter's ongoing failures to remediate the Colleague. Ulatowski stated that in late 2009, White was very concerned about the Office of Compliance's lack of communication with Baxter about the Colleague pump because White and the Company were awaiting affirmation or other response from the Office of Compliance regarding remediation timelines and related Colleague submissions made by the Company.

130. Despite their clear understanding that the Company's dialogue with the Office of Compliance had substantially and materially deteriorated, which signaled impending additional regulatory action in the face of repeated and definite statements by the FDA that the Company's remediation efforts were utter failures and that the Company's quality systems remained grossly deficient, Defendants revealed none of these facts to the market.

11. Baxter Failed to Pursue Remediation Efforts Related to the Colleague Infusion Pump Until it was Far Too Late

131. As set forth herein, the Consent Decree was entered into in 2006. Yet, as detailed by several Confidential Witnesses, Baxter failed to focus on remediation of the Colleague pump until

approximately late 2009. By that time, however, it was far too late for the Company to bring itself out from under the terms and conditions of the Consent Decree and present a satisfactory timeline to the FDA. Indeed, as set forth above, Defendants knew throughout 2009 that it would take at least several years for Baxter to complete its remediation efforts, and by October 2009, the FDA's Office of Compliance had "gone dark" in its communications with Baxter as it prepared to implement the Triple R.

132. For example, although Baxter created a Consent Decree office, it staffed the office with only four employees, two of whom were temporary employees. The Company's Consent Decree office was initially headed by Larry Gibbons ("Gibbons"), who oversaw quality systems for the Medication Delivery business. After approximately one year, Gibbons was replaced by Josef Mannhalter ("Mannhalter") who managed the temporary employees in the Consent Decree office and reported directly to White, the Corporate Vice President of Quality. White was responsible for overseeing all quality efforts at Baxter, including ensuring the quality and integrity of all products, building and managing a quality system with proper checks and balances, documenting design and reviewing the quality of documentation.

133. CW 1 recalled that while Baxter hired temporary or contract workers (mostly electricians and technicians) to fix problems with the Colleague pumps following the Consent Decree, this move was merely a "Band Aid" to the overall problem, which was an ongoing deficiency in the way the quality and engineering departments operated and communicated with each other.

134. Put simply, the Company did not want to do the work required to satisfy the FDA until it was too late. It was not until late 2009, well after Defendants knew Baxter was required to include ***clinical data*** in any Colleague-related 510(k) submissions, that Baxter began to commit the full resources and effort required to focus on remediation of the Colleague pump. Until that time

Baxter focused on creating additional pumps to take the place of the Colleague pump. These pumps included the Apex, Elizabeth, and Sigma, the latter of which Baxter acquired from another manufacturer and is now using to replace the Colleague pump as part of the recall.

135. The Apex project involved a next generation large volume pump under development, but no prototype was ever created. The project kicked off in or August 2007, when employees in Global Information Systems were gathered for a week at the Crowne Plaza Hotel in Mundelein, Illinois, to brainstorm and discuss Apex. CW 6 stated that the Apex project fell apart in December 2007 or January 2008 after the Company switched gears to devote more resources to working on an audit related to the Consent Decree with the FDA.

136. After the Apex project disintegrated, Baxter began working on the Elizabeth infusion pump, a next-generation infusion pump. Because Apex was initially supposed to be the replacement for the Colleague, elements from the Apex project were combined with the Elizabeth development. Instead of creating a brand new infusion pump from the ground up, which was the original plan for the Apex, the Company chose to modify and update the design of the existing Colleague pump head and use it for the Elizabeth pump.

137. CW 6 described the pump head as the "central brain," essentially the computer within the infusion pump. Infusion pumps can have one channel or multiple channels, but multiple channels are more desirable to hospitals because they can be used to administer more than one type of medication simultaneously. Therefore, part of the modifications to the pump head centered on the "UI" or the user interface, also known as the graphic display that communicates messages to the user. Instead of remediating the defective Colleague pump, the Company was modifying the "central brain" of the existing and maligned Colleague pump head and combining elements of the Apex project to create the Elizabeth pump.

138. Global Infusion Systems had been working on Elizabeth for some time, but in early 2009 the Elizabeth became a top priority in Global Infusion Systems and the Company assigned several people to work on its development. According to CW 6, at that time, Elizabeth became "the most important thing" in Global Infusion Systems.

139. Despite the Company's focus on developing new infusion pumps, as noted above, the Consent Decree enjoined Baxter from introducing or delivering any infusion pump that had components or device specifications in common with the defective Colleague or Syndio infusion pumps. Therefore, according to CW 6, there was no way the FDA would have approved – much less considered – the Elizabeth pump when the Colleague pump had not been remediated and was still posing dangers to patients in the United States.

140. It was not until the end of 2009, well after Defendants realized the FDA would no longer tolerate Baxter's incompetence and lame excuses, that Baxter urgently began to focus on fixing the problems with the Colleague pump, but by that time, Defendants knew it was too little, too late. Specifically, in late-2009 – three years after Baxter and Parkinson signed the Consent Decree and when it was crystal clear that the Company would have to conduct clinical trials ***prior to*** submitting a new 510(k) – the Company held a town hall meeting in the Company cafeteria that was attended by all Infusion Pump Development and Global Infusion System employees, including engineers, Vice Presidents and members of the Research and Development departments. CW 4 described the meeting as "all hands on deck." During this meeting, the employees were told that they were all to begin working on the Colleague infusion pump in an effort to comply with the FDA Consent Decree. Describing the content of the meeting, CW 4 stated there were clear indications that the Company was under great pressure to comply with the Consent Decree. Likewise, CW 8 recalled attending a June 2009 meeting where Khalili, a Vice President in Global Infusion Systems who led the Colleague remediation push, told employees they would be refocusing their efforts on

the Colleague to comply with remediation efforts tied to the Consent Decree. CW 8 stated it was generally known within the Company that the Company had been in talks with the FDA and that Baxter had a "distinct timeline" from the FDA by which to complete a resolution regarding the Colleague.

141. According to CW 6, after the late-2009 meeting, approximately 90 percent of employees within Global Infusion Systems were reassigned from whatever projects they had been working on to the Colleague remediation efforts, clearly demonstrating the urgency of the situation. Likewise, following the meeting, CW 4 estimated that approximately 60 to 70 Baxter engineers and "regulatory" personnel were involved in the Company's efforts to comply with the Consent Decree. According to CW 4, "everyone was working on Colleague" after the meeting. CW 6 confirmed that after the meeting it became obvious that the Company was suddenly very focused on Colleague remediation and was "scrambling" to put together its remediation efforts for FDA submission – the Colleague was never a top priority prior until the late 2009 meeting. CW 2, who worked at the Company from late 2009 until July 2010, estimated that during CW 2's tenure, there were about 100 employees in various jobs, including Engineers, Lab Testers, and Quality Assurance employees, among others, dedicated to remediation of the Colleague pump at the Round Lake, Illinois facility. Many, if not all, of these employees worked overtime on remediation efforts related to the Colleague pumps. The Company added several shifts so that employees were essentially working on remediation of the Colleague pump around the clock.

142. CW 2 explained that once the employees in Global Infusion Systems at the Deerfield, Illinois facility were assigned to work on Colleague pump remediation efforts, the stress level among employees skyrocketed. The schedule became considerably more grueling, there was intense pressure to meet deadlines, and the Company had people working on Colleague 24-hours a day, seven days a week. The suddenly urgent remediation efforts, which clearly demonstrate Defendants'

knowledge Baxter was failing miserably in its efforts to comply with the Consent Decree – and that the FDA was on the verge of a serious action against Baxter for its failures – were taking a toll on employees. Baxter employees were complaining about being stretched too thin and working very long hours on the Colleague pump, which led to burnout among employees. These facts were corroborated by CW 2 and CW 6.

143. When the Company's "eleventh hour" efforts were refocused on the Colleague pump remediation in late 2009, CW 6 recalled that the Company began holding ***daily*** morning meetings on the Colleague pump at its Round Lake, Illinois facility. These meetings were attended by all Managers and Engineers working as leads on the remediation efforts, and were held at 8:30 a.m. in Conference Room #340. Each meeting was attended by approximately 30 individuals, including the "leads" for Mechanical Engineering, Electrical Engineering, Systems, Software, Regulatory, Quality and essentially every department within Global Infusion Systems and Baxter's corporate offices that were working on remediation of the Colleague pump.

144. For example, CW 6 recalled that the meetings were attended by: Tom Penn ("Penn"), a project manager; Terese Frisch, a project manager who reported to Penn; Dean Andreakis, a software lead; Jamie Roman, a project lead overseeing remediation of the Colleague pump head; Robert Wasniewski, an electrical lead; Scott Evans, a quality manager; Ralph Labedz, a mechanical lead; Greg Leonard, a systems manager who joined the Company in September 2009; Tom Ryan, a project manager overseeing software remediation; Chuck Vecoli, a marketing representative who was promoted to an engineering position in Global Infusion Systems; Bjorn Elasser, a mechanical lead; Mark Lee, a director overseeing the software group within Global Infusion Systems who joined the Company in or around October 2009; Anu Paramsewarn, a testing engineer; Brett Todd, a systems lead; and several others. The meetings typically lasted thirty minutes to an hour and

essentially consisted of going around the room and discussing the status of various aspects of the remediation effort.

145. Additionally, during the last week of every month, Parkinson held a two day Monthly Management Meeting in the conference room adjacent to Parkinson's office. These Monthly Management Meeting changed locations between the Company's Vienna, Westlake Village and Deerfield, Illinois locations. All of the Company's division heads were required to attend the meeting in person. Approximately 12 division heads attended the Monthly Management Meeting, including Amundson, Medication Delivery President Peter Arduini, the President of the Renal Division, the heads of Legal and Human Resources, and the Vice President of Quality.

146. During the Monthly Management Meetings, each division head was given 15 to 20 minutes to present topics on what was going on within the Company. CW 7 created the report Amundson used to make her presentation regarding the BioScience business at the Monthly Management Meetings. The first section of the report, which was presented to the executive team, including Parkinson, included the "monthly numbers" for the BioScience division that CW 7 obtained from the Bioscience Controller. The report also included breakdowns of financial information by each of the five business lines within the BioScience division. This financial information was further broken down by geographic location for each of the five businesses. The financial information in the report was followed by a one page synopsis of the financial information. The final section of the report was a single page titled "Challenges and Successes," in which Amundson would discuss "ongoing issues" in the BioScience division. CW 7 recalled that Parkinson "definitely" used the reports to make sure he was "up to speed" on each division. In addition to the Monthly Management Meetings, the same executives participated in a Weekly Management Call every Monday morning at 8:00 a.m. Central Standard Time. There can be no

doubt that the Individual Defendants were briefed on the status of the Company's Colleague remediation efforts at these meetings.

147. In addition to this report, CW 7 assisted in preparing an 80-page PowerPoint presentation for Amundson that was used in the event Amundson had to explain the BioScience report in further detail. In addition to the Monthly Management Meetings, approximately one week prior to each month-end meeting, CW 7 recalled that Amundson held her own two-day meeting with Baxter employees that reported directly to her.

148. The inevitable conclusion of the Company's meetings in late 2009, including the "all hands" meetings, was that Baxter employees understood that the Company had to meet a strict FDA deadline for remediation of the Colleague pump in approximately January or February 2010. In fact, on more than one occasion, Khalili, one of the Vice Presidents of Global Infusions Systems, made statements that there would be "grave and dire consequences to the organization" and that "it would be catastrophic for the organization" if Baxter missed its 2010 FDA submission deadline. CW 6 recalled receiving a similar message from Keyzer, a manager in Global Infusion Systems, that the target to complete ***all*** remediation efforts throughout the Company was in January/February 2010. According to CW 6, by this point the Company had been working on the remediation efforts to satisfy the consent decree "on and off" for two years, but most remediation efforts take approximately five years to accomplish.

149. The foregoing accounts are based on the corroborating allegations of several Confidential Witnesses, and demonstrate that the Company did not begin its Colleague remediation efforts in earnest until late 2009 after the FDA mandated clinical data and as the FDA's Office of Compliance discontinued communication with Baxter regarding the Colleague pump as the Office of Compliance decided to implement the Triple R. Despite knowing its timelines were insufficient, that its quality systems violated the Consent Decree, and that Baxter would be unable to complete

clinical trials for at least several years, Defendants misled investors by consistently telling the market throughout the Class Period that the Company intended to and was on track to remediate its failed and defective Colleague pump. As the Confidential Witness allegations above demonstrate, it was, quite simply, a mad scramble within the Company at the end of 2009 (three years after entering into the Consent Decree), brought about by relentless pressure from the FDA, to hopelessly attempt to complete remediation of the Colleague during 2010. As set forth herein, however, Defendants were well aware that the Company's remediation efforts would take at least several years to complete, and that there was no hope of even submitting an acceptable 510(k), let alone exiting the Consent Decree in 2010

12. Defendants Knew Throughout The Class Period that Baxter Could Not Remediate the Colleague Pump for at Least Several Years, If at All

150. In addition to the specific meetings with the FDA outlined above, the corroborating accounts of well-placed Confidential Witnesses demonstrate Defendants' knowledge or reckless disregard of the fact that Baxter was at least years away from remediating the Colleague.

151. According to CW 3, following the 2006 Consent Decree with the FDA, Baxter became "resigned" to the fact that it could not increase its sales of infusion pumps in the market. Customers that had the Colleague infusion pumps retained the pumps until the expiration of the leases, but Baxter was banned from continuing to market the product. CW 3 stated that the Company initially had "target dates" for when the Colleague could be re-commercialized, but that the targets dates always passed without Baxter having a fix for the pump so that it could comply with the Consent Decree.

152. CW 3 further stated that by mid-2009, the Company "realized it was not going to get the Colleague infusion pump commercialized." In that regard, the Company began to market a line of infusion pumps made by Sigma, a competing manufacturer, which CW 3 described as a "decent"

replacement, but one that was not well known in the healthcare industry. According to CW 3, by marketing and selling the Sigma pumps, the Company had made an internal concession that it simply could not comply with the FDA Consent Decree. Defendants, however, never disclosed this concession, or its inevitable consequences to Baxter's financials and future business prospects, to the market.

153. Similarly, CW 6 strongly believed that Baxter executives knew in late 2009 that the Company would not meet its submission deadlines with the FDA. In that regard, CW 6 stated that Colleague software testing was still ongoing when CW 6 left the Company in January 2010. Likewise, CW 1 stated that as of December 2009 many remediation issues had still not been resolved. Indeed, just prior to Christmas 2009, Company engineers had completed some of the software testing and were starting to embark on systems testing, but they were finding numerous failures and non-conformances.[7] According to CW 6, there were "hundreds of failures, hundreds of issues related to testing" prior to Christmas 2009 that would have had to have been resolved before the Company could submit its remediation plan to the FDA. Put simply, the Company was nowhere near completing remediation of the Colleague pump.

154. Explaining the Company's relationship with the FDA as it related to the Colleague, CW 9, the former Senior Director and Interim Vice President of Research and Development, described the evolution of quality assurance cross-reporting for the Company's Medication Delivery and Renal businesses. In that regard, in 2004 or 2005, Baxter created a Design Center of Excellence, referred to internally as the "DCOE." The DCOE was created to oversee quality for the production of all medical devices by the Company, *i.e.*, enterprise-wide. CW 9 explained that prior to 2004,

[7] A failure meant deficiencies were found with the device while a non-conformance meant something was wrong with the way the test was written, meaning the test did not conform to the requirements of the device.

when the FDA started reviewing products, companies would "wall-off" the division responsible for the product under FDA scrutiny. Around 2004, the FDA took the position that entities either understood design control or did not. As a result, the FDA started looking at design control issues on an enterprise-wide basis. In response, Baxter created its DCOE, which was run by Executive Vice President of Research and Development Armstrong, to whom CW 9 had a direct line of responsibility.

155. In August 2009, however, Baxter gutted its DCOE, laying off between 100 and 160 employees in quality and product development roles within the DCOE. By that time, the Company's division presidents understood the "hot water" the Company was in with the FDA. Between 2005 and 2009, the FDA issued seven Class I recalls for problems regarding Colleague pumps, including software and hardware defects and battery failures. In that regard, CW 9 stated that Baxter had issued three successive releases of software changes for the Colleague infusion pumps and each software change was recalled.

156. Describing the culture at Baxter, CW 9 stated there were supposed to be "roughly" monthly meetings of DCOE employees, with the goal being to meet every three or four weeks. Instead, CW 9 stated the DCOE was "lucky" if it met every six or seven weeks. The result was that the operating people in the Company's various divisions stopped attending DCOE meetings: instead of 12 to 15 attendees, there were "maybe six." There was simply a lack of respect within Baxter for its own DCOE and its goals.

157. CW 9 recalled that by the beginning of 2009, at the latest, the Company knew it was not meeting FDA expectations. The Company knew it would have a very difficult time submitting any new fixes that had been validated for the Colleague. Expanding on the Company's problems, CW 9 first stated that because the FDA ordered so many recalls involving the Colleague, Baxter lacked credibility with the FDA. On top of that, the Company was only able to provide the FDA

with a "roadmap" of the processes it would undertake to fix the Colleague, but Baxter and the Defendants knew that it would take 10 to 15 months for Baxter to validate those processes. Given that the Company lacked credibility with the FDA and was still, in early 2009, only presenting a roadmap for unvalidated processes, CW 9 stated that the FDA was going to "slap" Baxter down. Indeed, CW 9 recalled that the Company remained unable to even understand and validate the software problems with the Colleague – as a result, the Company could only present the FDA with roadmaps for proposed, unvalidated solutions. Moreover, CW 9 recalled that, based on CW 9's conversations with Renal Division President Bruce McGillivray, Parkinson had candid conversations with McGillivray regarding ongoing issues with the Colleague infusion pump, and that Parkinson knew the Company's proposed fixes had not been validated.

13. The Hammer Falls: Fed Up with Baxter's Incompetent Remediation Efforts, the FDA Terminates the Colleague Through the Triple R

158. By no later than August 2009, the Company's remediation efforts were lagging so far behind schedule that Defendants knew it would take ***years*** for Baxter to successfully comply with the Consent Decree. As a result, on April 8, 2010, unbeknownst to the market, Baxter submitted a proposed correction schedule to the FDA stating that Baxter ***did not plan to begin*** its latest round of corrections to the adulterated and misbranded pumps ***until May 2012***. The proposed schedule also stated Baxter did not anticipate completion of the proposed corrections ***until 2013***. Despite the well-known health and very serious safety concerns surrounding the Colleague pumps, Baxter was proposing that it continue to be used on patients needing intravenous therapies until 2013 – at least seven years after entry of the Consent Decree.

159. The FDA found Baxter's proposal wholly unacceptable, and responded to Baxter with a letter on April 30, 2010 – which Defendants did not disclose publically until May 3, 2010 – noting that such a schedule would allow a device with well-known and serious safety concerns to remain in

use on patients in the U.S. healthcare system until 2013. Acting under authority given it by the Consent Decree, the FDA determined Baxter had failed to adequately correct, within a reasonable timeframe, the deficiencies in the Colleague pumps still in use, and ordered that Baxter: (i) recall and destroy all Colleague infusion pumps; (ii) reimburse customers for the value of the recalled devices; and (iii) assist in finding replacement pumps for those customers.

160. Therefore, although it surprised the market, causing a significant decline in the price of Baxter stock as artificial inflation was removed, it was no surprise to Defendants when, on May 3, 2010, the FDA required Baxter to recall and destroy all Colleague pumps existing within the United States.

C. The Plasma-Derivative Protein Products Industry

161. As set forth above, Baxter's BioScience business manufactures, among other things, recombinant and plasma-based proteins to treat hemophilia and other bleeding disorders, and plasma-based therapies to treat immune deficiencies. More specifically, the Company is a leading manufacturer of antihemophilic clotting factors to treat hemophilia, including recombinant and plasma-based factor VIII - the clotting factor missing from the blood of people with hemophilia A, and a therapy for people that develop inhibitors against clotting factor. Baxter markets its recombinant factor VIII under the name Advate.

162. Plasma contains many therapeutic proteins which the body uses to, among other things, fight infection, regulate body function, and control bleeding and clotting. The manufacturing process for plasma-derived therapeutic protein products ("plasma-derivative products") involves: (i) plasma collection; (ii) plasma testing; (iii) fractioning (*i.e.*, precipitation of solids by manipulation of solution pH, temperature, etc.); (iv) finishing or purification; (v) quality control; and (vi) lot release. The time required to complete the full manufacturing process ranges from seven months to a year.

Plasma-derivative products are essential for treating a number of serious illnesses. The annual cost for these treatments can exceed $90,000 per patient in some cases.

163. The manufacturing process is highly regulated because plasma products run the risk of containing and transmitting infectious agents. Regulators overseeing these plasma products include the FDA, state regulatory agencies, and the Plasma Protein Therapeutics Association ("PPTA"), an industry self-regulatory body.

164. Purchasers – usually hospitals through contracts negotiated by Group Purchasing Organizations ("GPOs") – of plasma-derivative products will pay very high prices if necessary to make essential treatment available to critically ill patients. The result is that small changes in production levels cause dramatic swings in prices for products, and producers stand to increase profits greatly by controlling output relative to demand. It is, therefore, of utmost importance to maintain competition in the industry so that there is ample supply of plasma-derivative products and the products remain fairly priced. Prior to and during the Class Period, however, Baxter engaged in a host of anti-competitive misconduct designed to improperly control and manipulate the United States market for blood plasma and plasma derivative products. To be clear, it is not the control and manipulation of the market for blood plasma and derivative products that gives rise to the fraud claims herein. Instead, it is Defendants' failure to disclose that these practices drove its margins, revenues, and future business prospects, and that its margins and revenues would shrink if the Company was unable to manipulate and control the market for these products, which underlies the fraud.

1. Defendants Use Artificially Inflated Margins and Temporary Boost in Demand to Mislead the Market as to the Performance and Future Business Prospects for Baxter's BioScience Business

165. In 2008, Talecris Biotherapeutics Holdings Corporation ("Talecris"), the third-largest supplier of plasma-derivative products, experienced certain manufacturing disruptions, including a

shortfall in supply. The result was that Baxter benefitted from the supply constraint by gaining market share and increasing the price of plasma-derivative products, which expanded Baxter's profit margins. Nonetheless, Talecris had previously announced in 2007 that it would aggressively expand its plasma production capacity in late 2008 and 2009. Prior to Talecris implementing its planned expansion, CSL Limited ("CSL"), the second-largest supplier of plasma-derivative products, entered into a merger agreement to acquire Talecris for $3.1 billion in August 2008.

166. In that regard, shortly before the start of the Class Period, on May 27, 2009, the Federal Trade Commission ("FTC") authorized a lawsuit to block the proposed $3.1 billion acquisition of Talecris by CSL, charging that the deal would be illegal and would substantially reduce competition in the United States markets for immune globulin, or "Ig," albumin, Rho-D, and Alpha-1.[8] On the same day, the FTC also sought a preliminary injunction in federal district court in the District of Columbia to stop the transaction pending completion of an administrative trial. *See Fed. Trade Comm'n v CSL Ltd.*, No. 09-cv-1000 at ¶ 41 (D.D.C. Nov. 11, 2009).[9]

167. The FTC's action came on the heels of an 8-month investigation into an illegal and anti-competitive price fixing cartel between Baxter and CSL. The agency's investigation resulted in

[8] Ig is a sterilized solution obtained from pooled human blood plasma, which contains the immunoglobulins (or antibodies) that protect against the infectious agents that cause various diseases. Ig supplements the body's natural response to infection in patients with compromised immune systems, *e.g.*, patients with acquired immune deficiency syndrome ("AIDS") and premature babies. When a patient is given Ig, the pooled antibodies from the various individuals who donated the blood to manufacture Ig help fight off or prevent infection in the patients. Albumin is the main protein found in blood plasma and is made by the liver. Albumin transports various essential substances in the blood, such as hormones, calcium, fatty acids, and other substances. Albumin also plays an essential role in the regulation of osmosis, which involves the movement of fluids in and out of blood vessels. An albumin deficiency can lead to serious medical issues, including edema and nephrotic syndrome.

[9] The initial version of the FTC complaint was filed under seal. On November 9, 2009, the unredacted version of the FTC complaint was made public. Several key documents from the FTC's action related to the merger are available at: http://www.ftc.gov/os/caselist/0810255/index.shtm (last visited January 27, 2011).

the gathering of materials, testimony, including from key company executives, and at least 21 declarations from witnesses associated with industry participants.

168. The FTC complaint was filed because the plasma-derivative products market had already undergone significant consolidation. With the ongoing market consolidation, the FTC noted how the plasma-derivative products market was functioning as a "tight oligopoly," with a "high level of information sharing and interdependence among firms." The FTC detailed how:

> [s]uppliers have learned they can maximize profits if each firm does its part to maintain overall industry "stability," holding back on expanding output to avoid driving prices lower. Firms closely monitor each other, collecting and cataloging an extraordinary wealth of timely competitive information, to ensure that all are engaging in desired "rational" and "disciplined" behavior. CSL and Baxter even have explored means of punishing firms that dare to "'break ranks' and chase market share."

169. Specifically, in the late 1990s, there were thirteen producers of plasma-derivative products. Facing sinking profits in the early 2000s, Baxter and CSL unlawfully agreed to exchange information regarding supply and production capacity in order to achieve the effect of reducing supplies and fixing prices. Baxter and CSL achieved their scheme by: (i) acquiring competitors only to close them down in order to reduce supply; (ii) using the PPTA, a trade association for plasma-derivative products manufacturers of which CSL and Baxter are important members, to take advantage of a data monitoring system that would allow them to determine current inventory and supply levels across the industry; (iii) signaling to each other the desirability of restricting supply; (iv) engaging in anticompetitive discussions involving supply and pricing issues at PPTA and other meetings; and (v) publicly denying supply shortages.

170. Over time, the market consolidated, and by 2003 the number of producers of plasma-derivative products had been reduced to nine. Today, there are only five producers of plasma-derivative products, with three of the producers, Baxter, CSL Limited, CSL Behring, and CSL Plasma (the last three collectively referred to as "CSL") and Talecris, controlling 85% of the plasma-

derivative products market.[10] The two additional producers of plasma-derivative products, Grifols, S.A. ("Grifols") and Octapharma AG ("Octapharma") are much smaller manufacturers, headquarted in foreign countries, with market shares in the single digits, and a limited ability to expand their presence in the United States.

171. Over the years, Baxter and CSL acquired numerous independent plasma collectors and facilities, and continue to do so. Soon after acquiring these facilities, both of the companies shut many of them down in order to reduce supply. For example, Baxter acquired Sera-Tec Biologicals LP in 2001 in order to ensure "[l]ong-term access to a consistent, stable source of plasma." In late 2002, Baxter acquired 42 plasma collection centers and a laboratory from Alpha Therapeutic Corporation. Baxter then closed 26 of its own plasma collection centers and 38 collection centers it acquired from Alpha Therapeutic, as well as a plasma manufacturing plant in Rochester, Michigan. Baxter and CSL's plan was simple – acquire the competition and then shut it down to restrict supply of plasma and plasma products.

172. In 2005, the American Red Cross exited the plasma products industry, with Baxter purchasing its existing supply of plasma. Market commentators and analysts have detailed the consolidation of the industry. For example, an investment firm detailed how "[a]bout 80% of the centers are now owned by plasma-products companies such as Baxter International, CSL Limited, Grifols, and Talecris Biotherapeutics. This represents a complete reversal in ownership since 2000, when 80% of the centers were independent enterprises." *See* Turner Investment Partners, "Will plasma products' prospects remain sunny?" (Feb. 6, 2008) *available at*

[10] CSL Limited is a biopharmaceutical company headquartered in Melbourne, Australia. Its subsidiary is CSL Behring. The company also operates CSL Plasma, one of the world's largest plasma collection networks, throughout the United States and Germany.

http://www.turnerinvestments.com/index.cfm/fuseaction/commentary.detail/ID/2500/CSI (last visited January 26, 2011).

173. Therefore, the plasma-derivative products industry as it exists today has significantly fewer suppliers than it did even six years ago and the remaining suppliers, most notably Baxter and CSL, are larger and more vertically integrated than ever before.

174. As consolidation occurred in the plasma-derivative products industry, prices increased in a straight-line correlation. Baxter and CSL were able to limit supply despite increasing demand, and consequently the companies were also able to manipulate significant price increases. Indeed, GPOs, distributors, hospitals, outpatient clinics and infusion centers, physicians—and ultimately patients—have all experienced tightening supplies and rising prices.

175. Baxter's efforts, in coordination with CSL, to restrict supply resulted not only in highly competitive pricing, but also extraordinary profits for Baxter, even as most other industries have experienced drastically lowered earnings in the face of the recent global economic crisis. Indeed, revenues from Baxter's BioScience unit climbed 12% to $1.36 billion in 2008, largely due to sales of plasma-based hemophilia and immune disorder treatments, vaccines and biosurgery products. Due to the profit its BioScience unit has generated, a news article by *The Associated Press* noted that "Baxter is one of a handful of stocks that have proven somewhat resistant to the global recession."

176. In order to maintain significant growth in market share and revenue, Baxter and CSL needed to ensure their coordinated ability to control the market by securing their positions as the only large suppliers of plasma-derivative products. By 2006, however, Baxter and CSL were faced with increased competition from Talecris. By this time, Talecris was the third largest supplier of plasma-derivative products and the only other company with the manufacturing capacity to potentially impact and increase the supply of plasma-derivative products. The emergence of Talecris

as another major producer of plasma-derivative products threatened the stranglehold Baxter and CSL had on the market for these products. Put simply, Baxter's pricing, margin, market share, and BioScience revenues were at risk if Talecris' rising production disrupted Baxter's carefully coordinated domination of the plasma-derivative products market.

177. As set forth above, in a 2007 SEC filing, Talecris made public its intention "to serve the overall market growth with incremental increases in production capacity" in 2008 and 2009. Talecris publicly stated its "goal is to be the recognized global leader in developing and delivering premium protein therapies to extend and enhance the lives of individuals suffering from chronic, acute and life-threatening conditions." The company planned to account for 45% of the industry's future output expansion over the next two years and was undergoing substantial expansion that had the potential to increase supply and lower prices of plasma-derivative products. Therefore, Talecris' announced business strategy was at odds with Baxter's intent to restrict supply of these products.

178. Baxter and CSL recognized the potential threat posed by Talecris. Therefore, in 2008, consistent with the previous pattern of ongoing industry consolidation, and with the intent of further controlling the market for plasma-derivative products by limiting industry production and maintaining high prices and margins, CSL and Talecris entered into a merger agreement, with Baxter's public support. In fact, in September 2008, Baxter CFO Davis publicly expressed the Company's view that CSL's attempted acquisition of Talecris would be "a positive stabilizing move within the industry."

179. Due to the controlled supply and high price of plasma-derivative products in the already oligopolistic industry, the FTC filed its complaint to block CSL's acquisition of Talecris. In a FTC press release accompanying the filing of its lawsuit, the Director of the FTC's Bureau of Competition stated that "[s]ubstantial consolidation has already occurred in the plasma protein industry, and these highly concentrated markets are already exhibiting troubling signs of coordinated

behavior. The proposed acquisition would further consolidate the industry and increase the likelihood of collusion."

180. Further, in its motion to place the complaint on the public record, the FTC stated "with the elimination of Talecris – the one firm that has consistently and significantly expanded output in the United States – CSL and Baxter . . . would face no remaining significant obstacle in their efforts to coordinate and tighten supply conditions for the relevant products, to the great detriment of consumers."

181. The FTC's investigation revealed and its complaint described, among other things, coordinated behavior between Baxter and CSL including signaling, *i.e.*, the intentional sharing of competitive information to ensure that manufacturers all restrain output and curb growth, resulting in higher prices for these products.

182. The FTC complaint also noted that Baxter and CSL focused on preventing an oversupply of plasma and that this control of capacity was critical in preventing price competition in the market. Therefore, the FTC remained firm in its allegations that the merger would have substantially lessened the competition in the already oligopolistic industry allowing the remaining suppliers, including Baxter, to continue to tighten supply and control the pricing of plasma-derivative products.

183. In the face of the FTC's efforts to quash the CSL-Talecris merger, on June 8, 2009, the companies publicly announced that they would abandon the proposed acquisition. The next day, Richard Feinstein, Director of the FTC's Bureau of Competition stated, "Yesterday's announcement is a tremendous victory for the patients who rely on these life-sustaining treatments. Rising healthcare costs are a burden to all too many Americans. Blocking this deal helps prevent additional price increases." He further stated, "If consummated, the proposed combination of CSL and Talecris would have increased the likelihood of collusion in these critical markets and led to higher

healthcare costs and reduced innovation. As shown in our court filings, Commission staff gathered an impressive amount of evidence and was fully prepared to demonstrate the anticompetitive harm that would have resulted from this acquisition."[11]

184. With the CSL-Talecris merger abandoned, Talecris resumed full production of its supply of plasma-derivative products. Thus, Defendants knew that by the summer of 2009, the temporary boost in demand and margins the Company had enjoyed with the merger was pending had ended.

185. The result of the FTC's action to stop CSL and Baxter's further anti-competitive behavior was that by the start of the Class Period, Defendants were fully aware their ability to tightly regulate and dominate the supply of plasma-derivative products had been compromised. Although Baxter enjoyed increased market share and pricing gains as a consequence of the cartel for plasma-derived products between itself and CSL –which translated to improved margins – at the start of the Class Period, Defendants knew the honeymoon was over because they knew that the merger between CSL and Talecris, and its commensurate decrease in product availability and increase in demand would not be consummated. With Baxter and CSL unable to eliminate Talecris as a formidable competitor, it was inevitable that Baxter would lose market share, lose its stranglehold on supply and demand (which would result in increased supply and decreased demand), and lose points from its swollen profit margins. In fact, by January 2010, Morgan Stanley recognized in a research report that "[s]hare volatility is increasing and has favored Talecris and CSL at Baxter's expense in the hospital segment of the market, which represents roughly 50% of the total market." Despite this, Defendants assured investors and the market that demand for the Company's plasma-derivative

[11] On June 15, 2009, the FTC and the two companies jointly filed a motion to dismiss the FTC's complaint, and on June 22, 2009, the FTC dismissed the complaint.

products was excellent, that its margins were stable and would continue to expand, and that the Company's BioScience division would experience substantial growth in 2009 and 2010.

186. The FTC's efforts to protect competition in the plasma-derivative products marketplace created a tidal wave of litigation against Baxter alleging that the Company engaged in anti-competitive conduct, including price fixing and manipulation of the supply of plasma derivative-products. On July 15, 2009, Pemiscot Memorial Hospital initiated a class action suit against Baxter and CSL alleging that the two rivals had created an illegal plasma cartel to engage in a conspiracy to fix the price of life-saving plasma derivative-products by restricting the supply of plasma, inflating the price of the products, and eliminating competition. By February 10, 2010, eighteen other plaintiffs had joined the class action lawsuit against Baxter and CSL. For example, on February 9, 2010, the Mayo Clinic, one of America's most prestigious and well-funded hospitals, filed a multimillion-dollar class action lawsuit against Baxter and CSL, which was consolidated with numerous related actions, claiming the companies were part of a damaging international cartel that fixed plasma prices.[12] The Mayo Clinic was the 19th plaintiff to join the civil action. On February 22, 2010, *ModernHealthcare.com* published an article entitled "Seeing red over plasma," which stated, in part:

> The Mayo Clinic is now among a dozen hospitals and systems gunning for the biggest producers of plasma-derived therapies, Baxter International and CSL. Those companies' behavior was cast in a suspicious light during a Federal Trade Commission action last year blocking further consolidation to a market it considered "troubling."
>
> The Mayo Clinic filed its lawsuit this month in U.S. District Court in Chicago, where a parade of lawsuits seeking class-action status recently were consolidated on a single docket. The lawsuits allege that CSL and Baxter coordinated output in order

[12] The matter is now proceeding before the Honorable Joan B. Gotschall in the United States District Court for the Northern District of Illinois, Eastern Division, as *In re: Plasma-Derivative Protein Therapies Antitrust Litigation*, Case No. 09 C 7666.

> to fix and raise prices, working largely through the industry's trade group, the Plasma Protein Therapeutics Association.
>
> Spokeswomen for CSL and Deerfield, Ill.-based Baxter issued statements calling the lawsuits baseless and promising to defend themselves aggressively. A lawyer representing the plasma association replied in an e-mail that the organization "has always acted in compliance with the antitrust laws. We are confident a court will agree."
>
> Last May the FTC filed an administrative challenge and sought an injunction in federal court to stop Australia-based CSL from buying competitor Talecris Biotherapeutics for $3.1 billion. The companies abandoned the deal in June.
>
> The lawsuits began appearing in federal courts the next month and heavily quote the government's analysis of the market for a handful of medically critical products derived from collected blood plasma, such as immune globulin. Portions of those documents remained under seal until late last year.
>
> "Suppliers have learned they can maximize profits if each firm does its part to maintain overall industry 'stability,' holding back on expanding output to avoid driving prices lower," the FTC asserted in its complaint. "CSL and Baxter even have explored means of punishing firms that dare to 'break ranks and chase market share,' " the FTC added in one of many portions initially redacted but made public in November. According to the government, CSL's bid for Talecris was driven by the smaller competitor's plans to increase production.
>
> The FTC argued in a motion seeking to make the full version public that "the relevant quoted language suggests a strong possibility of ongoing coordinated interaction between firms in the plasma industry." CSL, meanwhile, countered unsuccessfully that the FTC presented the citations "selectively and misleadingly."
>
> The Mayo Clinic, which declined to comment for this story, describes in its lawsuit that the system was concerned about the cost and availability of plasma products that are "critical to the health and survival of many of Mayo Clinic's patients," and the organization provided "substantial assistance and support to the FTC during the course of its investigation into the proposed merger."

187. The result of the foregoing is that Defendants knew at all times during the Class Period that Baxter's increased market share and revenues were the result of the iron fisted control Baxter had over the supply and pricing of plasma-derivative products in the market. The Company also knew, since June 8, 2009, that it had lost its ability to control the market due to the FTC's investigation and termination of the proposed CSL-Talecris merger.

188. Baxter had already anticipated this loss of market share and therefore, in 2009, Baxter tightened its hold on the market by manipulating plasma supply and took steps to actively lower the Company's intake of blood. This was a complete reversal of Baxter's announced policies just months earlier, prior to the abandonment of the CSL-Talecris merger. Specifically, in April 2009, prior to the FTC's complaint, Baxter held a BioLife Division meeting at the Hilton Hotel in Vienna, Austria. The meeting was attended by several BioScience employees, including employees from Global Sales and Amundson, the Company's then-BioScience President, who gave presentations during the meeting. According to CW 5, the meeting stressed how the Company was growing and how the Company had "nailed down" demand for the plasma-derivative products industry, as reflected in an internal analysis prepared for Baxter by an outside marketing firm.

189. Despite the positive news that was announced at the April 2009 meeting, by at least July 2009, just after the merger between CSL and Talecris was abandoned, the Company instructed its employees to take in less blood.

190. According to CW 5, who was told to reduce blood intake, the Company had several "levers" it could pull to "manipulate supply." The first lever was to lower donor fees. Prior to July 2009, donors were paid $20 for the first blood plasma donation of the week and $30 for the second donation of the week. But, in July 2009, the Company lowered its donor fees to $20 for the second donation of the week. The second lever employed to "manipulate supply" was to decrease the hours of operation at the Company's plasma collection centers. For example, beginning on January 1, 2010, CW 5 was instructed to decrease the hours of operation for the Elkhart, Indiana facility from 72 to 50 operating hours per week, including closing the collection center on Saturdays. The third and final lever employed by the Company to lower the manipulate supply and lower blood intake was to lower the marketing budgets for the Company's plasma collection centers.

191. The impact of the Company employing levers to manipulate supply was immediate and dramatic. For example, the plasma collection center located in Elkhart, Indiana, which had the capacity to collect 3,000 liters of blood per week, went from collecting approximately 1,500 liters of blood intake per week in April 2009 to approximately 700 liters per week by early 2010. According to CW 5, the facility had clear and easily achievable capacity for growth, but due to the Company's manipulation of the blood intake levers, the Elkhart facility was deliberately taking in less and less supply.

192. To be sure, the Company's plasma supply manipulation was Company-wide. CW 5 further confirmed that the supply manipulation levers were "pulled countrywide." In fact, some collection centers were given such reduced forecasts for blood collection that they were forced to close.

193. Expanding on the Company's manipulation of supply in 2009, CW 5 recalled that the Company's plasma collection center Operations Managers were tasked with forecasting the amount of blood the respective centers could take in on a weekly basis. Prior to 2009, the Company attempted to put together an annual budget of the amount of blood each center would take in. The annual budget set the amount of blood each sought to collect for the following year. These budgets were adjusted by each plasma collection center to "predict what you can do, not what we need." The goal of the forecasts and annual budgets was to provide the BioScience Division's manufacturing plant in Van Nuys, California an idea of how much blood the manufacturing plant could expect – "so they would know what is coming off the truck."

194. Prior to mid-2009, the adjustments were done on a quarterly basis. Eventually, this shortened to a monthly process by which the Company instructed the plasma collection centers as to how much blood the Company needed. CW 5 recalled that the forecasts started changing "every month," with the Company bringing down what it wanted collected, "bit by bit by bit." By early

2010, the forecast provided to the plasma collection centers was sent out every "couple of weeks" because the Company continued to request decreases in collections.

195. CW 5 described how during the time between the Company's 2009 meeting in Vienna and a similar meeting held in April 2010 at the Hotel Del Coronado in San Diego, California, the Company's focus had completely changed. The theme in 2009 was that the Company would grow "high and to the right." The theme in 2010 was to "hit the target." Unbeknownst to investors, the Company's focus had changed from growth (when the Company believed it could eliminate Talecris through the planned merger with CSL) to improving process (once the CSL-Talecris merger was abandoned). By that point, the reduction in demand for plasma-derivative products had already taken place.

196. According to CW 5, who communicated with the BioLife and BioScience divisions on a daily basis, the Company absolutely knew exactly how much blood it was taking in through its BioScience business. Every employee working in the BioLife and BioScience divisions was able to monitor the amount of blood collected in the Company's Daily Intake System ("DIS"), which provided a "day-by-day" breakdown of the amount of blood being collected Company-wide. The blood intake information was also available on the Company intranet, which showed for each collection center in the Company the percentage of blood collected above or below the budget forecast for each Center.

197. The foregoing allegations demonstrate that prior to the start of the Class Period, Defendants were able to effectuate a knowing manipulation of the plasma-derivative products market that served to artificially inflate the Company's BioScience business' financial results. By quashing supply and, consequently, boosting prices, Baxter enjoyed fattened margins and profits, which Defendants used to issue positive financial guidance, growth forecasts, and positive, materially misleading statements to the market. Defendants knew, however, that with disruption of

CSL's planned takeover of Talecris (which Baxter wholeheartedly supported), the Company's ability to manipulate the market and deliver sustained growth had been materially impaired. Put simply, it was inevitable that the Company would lose market share and that its artificially inflated profit margins would be trimmed down. Despite this knowledge, Defendants continued to assure the market that the Company was seeing strong demand, stable pricing, and that Baxter's margins would continue to expand. Even when chinks appeared in the armor in January 2010, when Baxter was forced to admit that pricing in the market was softening as supplies increased, Defendants did not come clean, and instead maintained their mantra of growth and steadfastedly maintained the Company's earnings guidance and estimates for financial performance. As a result, the price of Baxter stock was artificially inflated throughout the Class Period.

IX. DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS DURING THE CLASS PERIOD[13]

198. The Class Period begins on June 10, 2009. On that date, Baxter participated at the William Blair & Company Growth Stock Conference. Defendants Davis and Parkinson spoke during the conference on behalf of the Company. During the conference, an analyst with William Blair & Company discussed investors' concerns with the plasma market and how it was his belief that those concerns had been overplayed. In response, Davis made false statements about Baxter's BioScience division and, more specifically, the Company's plasma business, stating in pertinent part:

> Turning now to our businesses, I will start with BioScience, which is our largest business at $5.3 billion in sales and really encompasses several product areas, recombinants, plasma proteins, regenerative medicine, and vaccines.
>
> * * *

[13] In order to not just plead Defendants' false and misleading statements without any context, Plaintiff has attempted to provide the Court with context in this section by bolding and italicizing Defendants' statements Plaintiff contends are false and misleading.

> Turning to the plasma business, this is a business obviously has been alluded to where we have received a lot of the questions recently. I would refer you back to the comments that our CEO Bob Parkinson made about this business on our first-quarter earnings call and some of the comments he had as well as the guidance he gave for this business at that time.
>
> ***It is important to note our views of this business have not changed. We continue to see robust growth in demand and we believe this business will drive revenue growth approximating 10% overall long-range plan, which has consistently been where we have seen this business going forward.*** And it is important to note that this will come from the fact that this business continues to see favorable demographics much like hemophilia. It is still a fairly underpenetrated disease on a global basis. We are driving for better awareness and diagnosis of this therapy. We continue to drive for further on-label indications, ***as I mentioned earlier, and we have the geographic expansion opportunities which just now as we start to finally get to a point -- we really are not leading or living anymore hand to mouth on plasma supply, we can really start to now go after latent demand in the emerging and developing markets, which we see as an area of growth for the Company.***
>
> ***So if you look at this business, the fundamentals continue to remain very solid and our confidence in this business is unchanged. I think that is really an important point for you all to take away.***

199. As the conference continued, analyst Ben Andrew discussed the failed Talecris-CSL merger, and stated in pertinent part, as follows:

> [C]ancellation of the Talecris CSL deal is -- you can spin it two ways. One, it's bad because you are still going to have an extra competitor out there. You are still going to have Talecris as a private-equity backed organization. Maybe you would rather not have them be kind of wondering what their end game is if you will. But on the other side, Talecris and all the players, they are motivated to maintain a healthy market for these products, grow demand, and keep the incentives to grow supply in plays such that patients can see increased demand for a product over time.
>
> And there's two ways to screw this market up. You can oversupply it and you can undersupply it, both of which ultimately hurt patients, just in different ways. That is what I think is very difficult for people to grasp about this market. Having a healthy balance on supply and demand is a good thing. It's not anticompetitive, but it's hard to make that argument when you are standing in front of a grand jury, if you will.
>
> So in any event I can say that. They can't. That's my opinion, but I think this is broadly good news for the industry and again, Talecris is motivated not to do something that would damage the overall availability of product for patients over time.

200. In response, Davis further discussed plasma supply, stating in pertinent part:

> ***Having a sustained supply of product and having an economically stable market to allow for that sustained supply product allows us to do what is our primary mission, which is to take care of our patients.*** And I think as we talk internally, that is something we always come back to and I think that in the popular press it's somehow been lost. I can tell you if you go to members of the Primary Immune Deficiency community, they are worried when they hear discussions like what we are having right now, because all they want to know is this is a life-sustaining therapy. Is it going to be there for me in the future? And that is what Baxter is committed to.
>
> We believe now we are in a position to be able to do that. ***We will drive our supply of products to meet that growing demand and importantly as we have said, whether it be the demographics, the fact that there still is a lack of awareness in total amount of prescription for that therapy as well as the new indications we are driving for, the demand demographics, the demand drivers are there. They are robust. They are deep. We focus on that and how can we continue to maintain them and accelerate them. And I'm confident we can do it and as long as we can do that, this will be a very robust business for Baxter.***

201. At the end of the conference, Davis discussed Baxter's deal with SIGMA and the remediation of the Colleague pump, stating as follows:

> The key here is we look at the value that the SIGMA pump brings to us. It is -- that it allows us options. We now can go out and where we have a hospital that is looking to go to a competitor, we now have an option because actually if you go out in the marketplace today, ***there's still 200,000 roughly COLLEAGUE pumps in the marketplace. And generally hospitals are satisfied with the product.***
>
> ***The only real issues we hear are either, a, we need to expand our pump base, can you give us more pumps? Which we cannot.*** Or the battery life because of the upgrades we made to the software programming for safety have shortened the battery life of the product because obviously you are using more programming time. And when will we have a product with newer battery technology which is our next generation product we are working on?
>
> So as you look at it, what we like about SIGMA is it allows us to go to those customers and say we have an option for you and then we can bring all of the other services of Baxter. ***As far as COLLEAGUE, right now we continue to be committed to remediating that product and working through that and that is part of the strategy as well.*** Any decisions around that we leave to the future.

202. The statements referenced in ¶¶198-201 were each materially false and misleading when made because they represented and/or omitted adverse facts which then existed and disclosure of which was necessary to make the statements not false and/or misleading. The true facts, which were known to or recklessly disregarded by each of the Defendants, were:

- Defendants' view of Baxter's plasma business certainly had changed. Rather than continuing "to see robust growth in demand" that would "drive revenue" through "solid fundamentals" that left Defendants' "confidence in this business. . . unchanged," Defendants knew there had been a seismic shift in the Company's plasma business outlook. This was because Baxter's revenue growth was due in large part to the Company's ability to manipulate plasma-derivative products supply and tightly control of pricing for the products, in coordination with CSL, that resulted in artificially inflated profit margins. When the CSL–Talecris merger was abandoned as a result of the FTC action (just prior to the start of the Class Period), which exposed Baxter's anti-competitive misconduct, Defendants knew that Baxter would lose market share as Talecris stepped up production, and Defendants further knew that Baxter had lost its ability to manipulate supply and control pricing. Therefore, the Company's projected financial performance lacked a reasonable basis and was illusory and misleading in light of Defendants' knowledge of changed economic circumstances.

- The Company and its largest competitor, CSL, had been working together for years in an effort to control and manipulate the market for plasma in the United States. With the failure of the Talecris merger, however, Defendants knew the Company's control of the plasma market would be substantially weakened, and that the Company's ability to control supply and manipulate pricing would likewise falter. Defendants, however, omitted this material information from their Class Period statements to the market.

- Defendants knew that in the face of the defeated merger, Baxter's profit margins were no longer sustainable and would inevitably shrink. The consequence of these events was that Defendants lacked a reasonable basis for their statements regarding the strength of the plasma market, the expectations for demand, and the Company's financial outlook and future business prospects.

- The Company was not positioned to "drive [its] supply of products to meet that growing demand." Quite the opposite, Defendants knew the Company was internally ratcheting down plasma collection in order to attempt to maintain a plasma supply shortage. With Talecris reemerging in the competitive landscape at the start of the Class Period – which dealt a blow to Baxter and CSL's cartel – Defendants knew it was only a matter of time before Baxter lost its ability to manipulate supply and control pricing, at which point the Company would lose market share, face falling prices for its products, and experience contraction in its critical profit margins.

- Defendants' statements regarding the Colleague, including that "hospitals are satisfied" with the Colleague, were riddled with material omissions. At the time of their false and misleading statements, Defendants were well aware the Company was not focusing on its Colleague remediation efforts with any degree of urgency. Indeed, it was not until late 2009 that Baxter committed sufficient resources to remediation of the Colleague. At the time of Defendants' statements, the Company simply was not "committed to remediating that product." Moreover, as detailed by the CW and former FDA employee allegations herein, Defendants were well aware by the beginning of the Class Period – at the latest – that it would take the Company

several more years to remediate the Colleague. Indeed, at the time of these statements, as well as throughout the Class Period, the Colleague was plagued by endless deficiencies and non-conformances. The Company's quality systems were also deficient and not in compliance with Part 820. As a result, Baxter was incapable of even submitting an acceptable 510(k) based on verifiable and validated data.

- Defendants omitted the critical fact that since November 25, 2008, the FDA required Baxter to submit clinical data to supplement the Company's future 510(k) submissions for the Colleague pumps, and that the clinical data would have to demonstrate that the changes to the Colleague were safe and effective. The clinical data condition for Baxter's future Colleague 510(k) submissions was an unusual requirement stemming from the Company's history of failed remediation attempts that resulted in additional Class I recalls, as well as the fact that the FDA did not trust Baxter to actually fix the pumps, viewed the Company as incompetent at remediation, and had "no faith" in Baxter's ability to adequately simulate clinical use.

- On top of omitting the clinical data requirement for Colleague remediation, Defendants omitted that because Baxter lacked Part 820 compliance, it did not have the necessary quality systems to even undertake clinical trials that would produce the credible clinical data required by the FDA since November 25, 2008. Defendants were well aware that the lack of Part 820 compliance would seriously undermine the FDA's confidence in the Company's processes for collection, verification, and validation of data that would be submitted in a 510(k).

- Defendants were fully aware that it would take the Company at least a couple of years to generate the clinical data required for a 510(k) submission. Without such clinical data, the FDA would have rejected any Colleague remediation plan proposed by the Company.

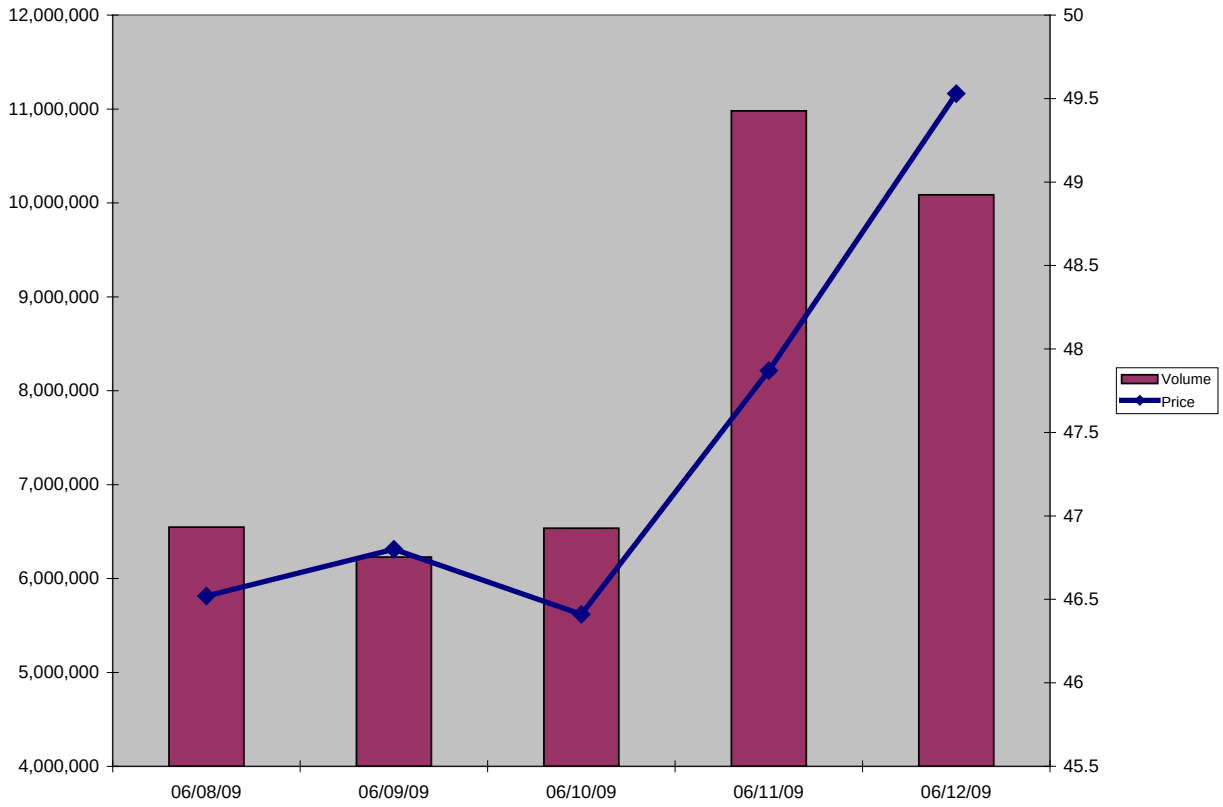
- The FDA consistently and unequivocally informed Parkinson and other Baxter representatives that the Company's efforts to remediate the Colleague were grossly insufficient and that the Company's timeline for remediation was completely unacceptable. In addition, during March 2009, the FDA informed Baxter that its CAP supplement (Baxter's proposal for remediating the triple channel Colleague pumps) was rejected and the FDA notified Baxter of an "additional escalation" when it requested a timeline for how Baxter proposed to remediate the triple channel Colleague pump. Despite Defendants' clear knowledge that the Colleague issues had grown even worse, and that during April and May 2009 the FDA provided Baxter with written questions regarding the reasons behind Baxter ongoing Colleague remediation delays, Defendants falsely told the market that Baxter was "committed to" remediating the Colleague.

- At all times during the Class Period, the Colleague remained a violative device whose numerous defects, deficiencies, and heath risks were "intolerable," causing an unacceptable rate of death and serious injuries in patients treated with the Colleague pump.

- Defendants knew Baxter was incapable of remediating the Colleague pump due to the Company's archaic documentation systems, lack of coordinated databases and software, lack of communication among Company divisions, design traceability issues, and high management turnover, among other things. The combination of these many factors provided Defendants with knowledge that Baxter was incapable of remediating the Colleague pump in accordance with the Consent Decree.

- As a result of the foregoing, Defendants lacked a reasonable basis for their positive statements about the Company, revenue projections and financials, as well as its future business prospects.

203. In response to Defendants' false and misleading statements, on June 11, 2009, the price of Baxter common stock rose $1.46 per share, or 3.15%, from a closing price of $46.41 on June 10, 2009 to close at $47.87 per share on June 11, 2009, on heavy trading volume, as set forth in the chart below:



204. On July 16, 2009, Baxter issued a press release reporting strong financial results for the second quarter of 2009 and raising its full-year financial outlook. The Company stated, in pertinent part:

> In the second quarter, BioScience revenues totaled $1.4 billion, which represents a 2 percent increase over the prior-year period. Excluding foreign currency, BioScience sales advanced 13 percent, reflecting strong double-digit gains across several core franchises, which offset weak sales of the company's FSME vaccine, primarily in Germany. ***Key drivers of this performance include robust growth of antibody therapies and other specialty plasma therapeutics, strong sales of recombinant therapies, including ADVATE [Antihemophilic Factor (Recombinant), Plasma/Albumin-Free Method] for the treatment of hemophilia, as well as biosurgery products.***
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> * * *
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> **Third Quarter and Full-Year 2009 Outlook**
>
> Baxter also announced today its guidance for third quarter 2009 and updated its guidance for the full year.
>
> ***For the third quarter of 2009, Baxter expects sales growth, excluding the impact of foreign currency, of approximately 7 to 8 percent. Based on current foreign exchange rates, the company expects reported sales including the impact of foreign currency to be approximately flat over the prior-year period. Baxter also expects to achieve earnings per diluted share of $0.95 to $0.97, before any special items, in the third quarter.***
>
> ***For the full year, Baxter continues to expect sales growth, excluding the impact of foreign currency, to be approximately 7 to 8 percent. Based on current foreign exchange rates, Baxter expects reported sales growth to be approximately flat. In addition, the company now expects earnings per diluted share of $3.76 to $3.80, before any special items, and continues to expect cash flow from operations to total more than $2.6 billion.***

205. Following issuance of the press release on July 16, 2009, Baxter hosted a conference call to discuss its second quarter financial results and operations. Each of the Individual Defendants participated in the call on behalf of the Company. During the call, numerous false and misleading statements were made that were designed to artificially inflate the Company's stock price. For example, commenting on the Company's financial goals, Parkinson stated, in pertinent part:

> ***While we continue to be very vigilant in monitoring the landscape in which we operate, to date we've not experienced any meaningful macroeconomic impact on the underlying demand for our products. As I've mentioned to you all in the past, we continue to believe that we are well positioned, given both our geographic reach and the medically necessary nature of our product line, to meet financial objectives in both the short and the long term.***

206. Davis discussed the Company's Medical Delivery and BioScience divisions, stating in part:

> ***Turning to the Plasma business, we continue to see strong underlying fundamentals and robust growth across our Plasma portfolio. Plasma Proteins sales of $353 million increased 21%; and excluding the impact of foreign currency, Plasma Proteins sales grew 38%.***
>
> ***Performance continues to be driven by strong demand globally across the portfolio for all proteins including FEIVA, albumin, plasma-derived factor VIII, and Aralast.***
>
> Antibody Therapy sales increased 9% to $344 million; and excluding foreign currency, Antibody Therapy sales grew 14%. ***This growth is the continued result of strong global demand, favorable mix, and pricing.***
>
> * * *
>
> ***As a result of gross margin expansion and operational leverage, our operating margin of 23.9% reflects an improvement of 40 basis points sequentially and 190 basis points versus the prior year. It is also in line with our full-year guidance of 24%, which represents a historic level for the Company.***

207. As the call continued, Davis discussed Baxter's financial outlook and guidance for 2009, stating in part:

> First, as you saw in the press release, we now expect earnings per diluted share of $3.76 to $3.80. More specifically, ***we now expect full-year sales growth excluding the impact of foreign currency of approximately 7% to 8%; and we expect our reported sales growth to be approximately flat to 2008.***
>
> * * *
>
> ***For BioScience, we expect sales growth excluding foreign currency to be in the 10% to 12% range. This will be driven by high single-digit growth in Recombinant sales, high-teens growth in the Plasma Protein and Antibody Therapy businesses, and mid-teens growth in Regenerative Medicine.***

208. During the question and answer portion of the call, when asked to discuss pricing in the Plasma Protein business, Parkinson stated, in pertinent part:

> Yes, I don't want to get into specific details on pricing in the Plasma Protein business, Bob. What I would say is the following.
>
> First of all, you saw continued robust growth of our overall Plasma Protein business in Q2, including the Antibody Therapy sector. ***I would also tell you that our***

> ***margins for Plasma Proteins and also Antibody Therapy improved Q2 versus Q1. They improved in the US as well as O-US.***
>
> ***So our position consistently has been the outlook for this business continues to be robust. Our position has not changed at all on that over the recent months. So we continue to be very confident about the future growth of this business. So that's about as detailed as I'm going to get on the pricing discussion this morning.***

209. In response to a question from a Bank of America analyst, regarding a possible formal investigation into improper and anticompetitive signaling in the plasma industry between Baxter, Talecris and CSL, Parkinson evaded the issue and stated as follows:

> Yes, I have no idea. Obviously given the merger, the FTC was not only involved with the two companies in question, but we've received a request -- as did other companies in the industry -- as part of that overall assessment by the FTC. But anything above and beyond that, not really going to comment on.

210. Regarding strong growth in the Company's plasma proteins business during the quarter, Parkinson further stated, in pertinent part:

> You know, actually ***we are forecasting***, Bob, ***continued strength***, as I mentioned, ***for the rest of the year.*** The business becomes a little bit spiky sometimes based on tenders that may hit in particular quarters.[14] But if you look at the components of the broader category, including FEIVA and Aralast, albumin, plasma-derived factor VIII for some of the reasons that I mentioned in my response to Matt's earlier question and so on, frankly ***growth in all the subsegments of Plasma Proteins -- including obviously Antibody Therapy -- continue to be very strong.***

* * *

211. Joining in, Ladone stated:

> Yes, we did have some tenders that hit in Q2. ***But I would tell you that even if you excluded those tenders, the growth in the quarter was extremely strong for our Plasma Proteins***.

212. Later in the conference call, Parkinson confirmed that Baxter raised guidance for both plasma proteins and antibody therapy for the year, from mid-teens growth to high-teens growth.

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[14] A "tender" is a supplier's offer in a public procurement. By extension, a request for a tender refers to a structured invitation by governments or government agencies to suppliers for the supply of goods or services.

Parkinson also agreed that by raising guidance, the Company was giving its strongest comment on the outlook for the plasma markets. Discussing the outlook for the BioScience division, Parkinson also stated in relevant part:

> ***I mean I think it's part of our general outlook for the growth of the category, which again we consistently described as robust. I mean we see the margins not only holding but improving over time due to a variety of factors.*** Whether it's product upgrades, whether it's yield improvements, pricing stability, and so on. We can only say that so many different ways, I guess.

213. Further commenting on the Company's future business prospects in light of healthcare reform, Parkinson stated, "given the medically necessary nature of our products, ***very candidly we don't see anything really fundamentally affecting demand***."

214. Later in the call, David Lewis, an analyst with Morgan Stanley, commented on the strong United States plasma proteins market and the slightly weaker outside-United States IVIG market. Lewis asked "[j]ust clearly again, you are not seeing any emerging market weakness, pricing or volume, on the IVIG front internationally? And there is nothing going on in US albumin or broader proteins that drove a very strong quarter?" Davis responded ***"[t]he answer to both is frankly no."***

215. Davis also discussed the Colleague pumps, and a slight erosion in share, stating in pertinent part, "we haven't seen a material erosion of share, but we are continuing to see a slight erosion of share. And that is impacting the sets."

216. Market analysts were clearly swayed by Defendants' false and misleading statements. On July 16, 2009, J.P. Morgan issued an analyst report in response to Baxter's second quarter 2009 results, stating that "[f]or those concerned about the health of the plasma proteins market, we think *there couldn't have been a stronger statement than Baxter's decision to raise its '09 guidance today.* Market analysts from William Blair & Company agreed, stating that the plasma market *"is stable and that the field supply and demand remains well balanced for the industry."*

217. On July 28, 2009, Baxter filed its quarterly report on Form 10-Q for the quarter ending June 30, 2009, which confirmed the previously announced financial results and was signed by Davis and Parkinson (the "Second Quarter 10-Q"). The Second Quarter 10-Q contained required Sarbanes-Oxley certifications signed by Davis and Parkinson stating that the Form 10-Q did not include any material misrepresentations. Discussing the Colleague pump, the Second Quarter 10-Q stated, in relevant part:

> ***With respect to COLLEAGUE, the company remains in active dialogue with the U.S. Food and Drug Administration (FDA) about various matters, including the company's remediation plan and reviews of the company's facilities, processes and quality controls by the company's outside expert pursuant to the requirements of the company's Consent Decree. The outcome of these discussions with the FDA is uncertain and may impact the nature and timing of the company's actions and decisions with respect to the COLLEAGUE pump.*** The company's estimates of the costs related to these matters are based on the current remediation plan and information currently available. It is possible that additional charges related to COLLEAGUE may be required in future periods, based on new information, changes in estimates, and modifications to the current remediation plan as a result of ongoing dialogue with the FDA.
>
> * * *
>
> The company began to hold shipments of COLLEAGUE infusion pumps in July 2005, and continues to hold shipments of new pumps in the United States. Following a number of Class I recalls (recalls at the highest priority level for the U.S. Food and Drug Administration (FDA)) relating to the performance of the pumps, as well as the seizure litigation described in Note 6, the company entered into a Consent Decree in June 2006 outlining the steps the company must take to resume sales of new pumps in the United States. Additional Class I recalls related to remediation and repair and maintenance activities were addressed by the company in 2007 and 2009. The Consent Decree provides for reviews of the company's facilities, processes and controls by the company's outside expert, followed by the FDA. In December 2007, following the outside expert's review, the FDA performed an inspection and remains in a dialogue with the company. As discussed in Note 3, the company has recorded a number of charges in connection with its COLLEAGUE infusion pumps. It is possible that additional charges related to COLLEAGUE may be required in future periods, ***based on new information, changes in estimates, and modifications to the current remediation plan as a result of ongoing dialogue with the FDA***.

218. The statements referenced in ¶¶204-15, 217 were each materially false and misleading when made for reasons set forth in ¶202 and the factual detail contained throughout this

Complaint. In addition, the statements referenced in ¶¶204-15, 217 were materially false and misleading when made because they represented and/or omitted adverse facts which then existed and disclosure of which was necessary to make the statements not false and/or misleading. The true facts, which were known to or recklessly disregarded by each of the Defendants, were:

- Defendants lacked a reasonable basis to forecast "continued strength" and growth in the plasma-derivative products market – or in the Company's gross margins – and, further, had no reasonable basis to raise Baxter's financial guidance. Defendants were fully aware the failure of the CSL–Talecris merger eliminated the Company's ability to manipulate supply and control pricing, and that Baxter was losing market share as a result.

- Despite their knowledge of changed economic circumstances in the Company's crucial plasma business, Defendants continued to tout the Company's consistent and unchanged outlook for increased demand, expanding margins, and future growth. Indeed, at the time of Defendants' statements, the Company was actively taking measures to deliberately decrease plasma production.

- Once CSL and Talecris announced the abandonment of their merger, Defendants knew that Talecris, the third largest supplier of plasma-protein products, would follow through on its announced intentions to increase the supply of plasma-derivative products, thereby meeting demand, and causing prices to drop. Therefore, Defendants knew the Company's prior margin expansion would not continue, but Defendants materially mislead the market by forecasting continued sales growth, favorable pricing, and improved margins.

- Defendants were well aware that the outcome of Baxter's discussions with the FDA was extremely negative. Without fail, the FDA consistently told Baxter, and Parkinson specifically, that the Company's Colleague remediation plans were insufficient and that Baxter's timelines were far too long. In meeting after meeting, the FDA directly expressed both its rejection of Baxter's remediation plans and its lack of tolerance for Baxter's ongoing failure to achieve successful remediation of the Colleague pumps.

- Despite raising the issue of the Company's dialogue with the FDA, Defendants omitted that as a result of that dialogue, Defendants explicitly knew by November 25, 2008 that Baxter was required to submit clinical data in support of any future Colleague-related 510(k) submissions. Without such clinical data, which Baxter had not even received authority from the FDA to obtain (and which would take a couple of years to compile), Baxter's Colleague remediation efforts were, without question, destined for failure.

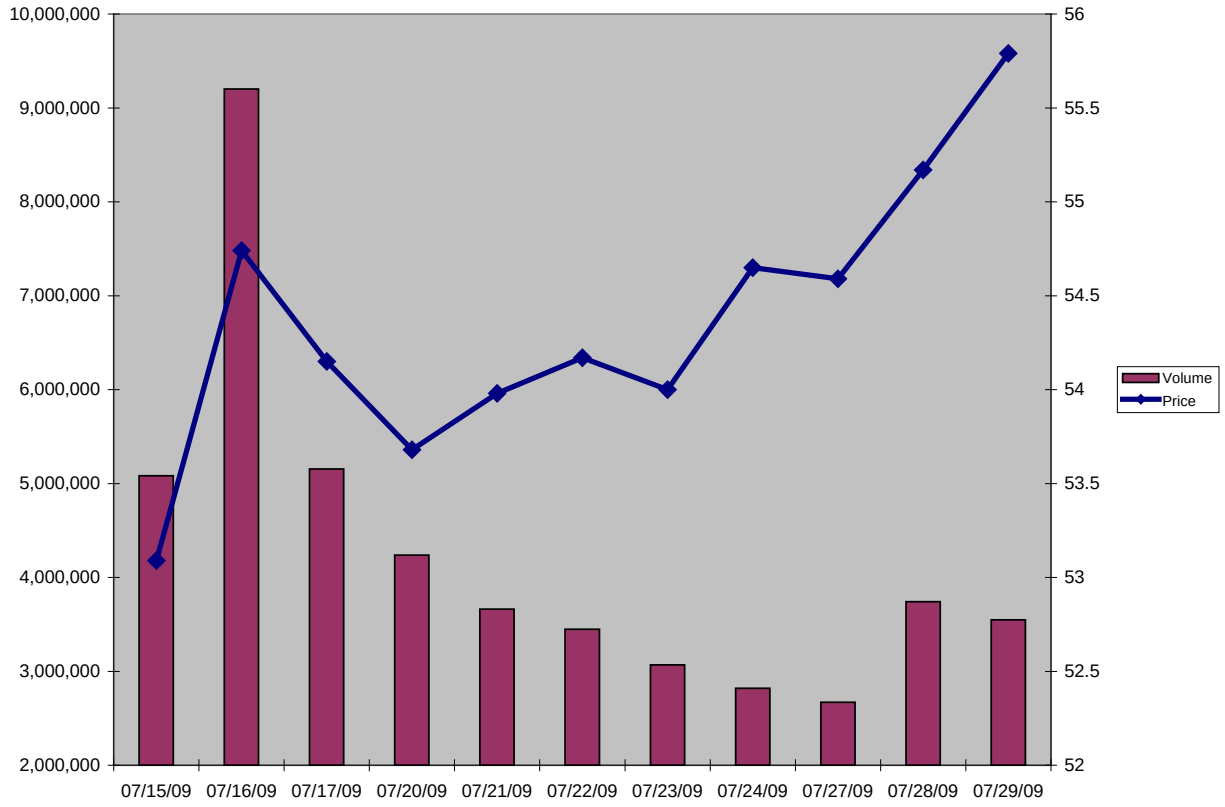
- Although Defendants purported to warn that there could be "modifications to the current remediation plan," Defendants had actual knowledge that the Company did not have a remediation plan accepted by the FDA. Put simply, there was no "current

remediation plan." Indeed, the FDA rejected Baxter's CAP supplement, rejected each of Baxter's proposed remediation timelines, and, to the extent Baxter did implement "fixes" for the Colleague, those fixes only led to additional defects and Class I recalls. Moreover, the Company was incapable of submitting a 510(k) because it had no clinical data, which would take years to obtain. In that regard, Baxter had not yet submitted a pre-IDE, which was required to even begin a clinical trial. Even assuming Baxter had clinical data in hand demonstrating that the Colleague remediation plans were safe and effective – which it clearly did not – Baxter's ongoing quality systems deficiencies would have undermined the credibility and veracity of the data in any 510(k) that the Company did submit.

- Defendants were fully aware that the Company was no closer to actually remediating the Colleague than it had been in the past. In that regard, in addition to not having clinical data, a 510(k), or a pre-IDE, during a June 11, 2009 meeting, Baxter presented a Colleague remediation timeline to the FDA that had both remediation and deployment efforts for the new Colleague pushed further back. Baxter was told at that meeting that its proposed timeline was unacceptable because the remediation was taking too long and needed to be expedited. Defendants, however, disclosed none of these facts to the investing public.

- As a result of the foregoing, Defendants lacked a reasonable basis for their positive statements about the Company, revenue projections and financials, as well as its future business prospects.

219. In response to Defendants' false and misleading statements, the price of Baxter common stock rose $1.65 per share, or 3.11%, from a closing price of $53.09 on July 15, 2009, to close at $54.74 per share on July 16, 2009, on heavy trading volume, as set forth in the chart below:



220. On September 16, 2009, Baxter hosted an investor conference for analysts, media representatives, and investors. Defendants Parkinson and Davis participated in the September 16, 2009 investor conference, and repeatedly assured investors about the Company's ability to meet its long-range plans. For example, Parkinson stated, in pertinent part:

- ***"As you may recall, when we met here in May of 2005, we framed the growth potential of our existing portfolio of businesses. You may remember that we shared our Base Case Long-Range Plan that projected at that time about 5% annual compounded revenue growth over a five-year Long-Range Plan period. At that time, we also discussed our aspiration to exceed that objective through a variety of initiatives. Two years later, in March of 2007, we updated that Long-Range Plan sales growth to approximately 7% . . . .*** [We believe that our current normalized rate of revenue growth has increased to the **7** to 8% range going forward. ***This provides the new Base Case platform for which to view our future."***

- ***"Of course, while we focus our efforts on disciplined growth acceleration, we've remained diligent ensuring that we continuously improve margins and drive annual EPS increases at a faster rate than revenue growth. Our confidence in that assertion will I believe be reinforced by the various presentations that you'll hear throughout the day."***

221. Discussing Baxter's outlook, Davis stated, in pertinent part:

- ***"[O]ur management team has a fabulous track record of meeting or exceeding our key financial objectives . . . . Incorporated in our plan is our expectation of continued margin expansion, which provides us with the flexibility to invest in select programs and also enhance our short-term and our long-term growth."***

- "[W]e're proud of our sustained success in meeting or exceeding our financial commitments despite a very challenging global economic climate that has developed. ***We've achieved record sales resulting in an acceleration of normalized sales growth over the last several years. This success validates the strength and value of our diversified business model and illustrates the solid fundamentals underpinning our portfolio."***

- "***In BioScience, we expect revenue growth of 7 to 9%*** as we focus on improving access to care and standards of care and drive differentiated value with expanded indications and the development of new therapies."

- ***"We expect to see continued gross margin expansion across all businesses and regions over the Long-Range Plan. One of the most frequently asked questions we receive is, given the improvement in gross margin is the margin sustainable and can it expand even further? Well, the answer is yes. As we've frequently mentioned, there are a number of levers that will drive meaningful gross margin expansion over the Long-Range Plan."***

- ***"Margin improvement has largely been driven by the strength of our BioScience business, which has been our largest and fastest growing business and is also the highest margin business in the company. Another question we frequently receive from investors is in regard to price improvement and the impact that they've had on our gross margin improvement. We believe many investors focus on this given the recovery we've experience[d] in the plasma market over the last several years, without fully appreciating the breadth and depth of other margin drivers such as improved product mix, product upgrades, lower cost and improved yield***. While price alone has accounted for approximately 25% of the company's overall percentage margin improvement since 2006, other catalysts drove approximately 75% of that change as we've reached the margin of over 50% in 2008."

222. Parkinson further added:

In terms of the plasma business, really not a lot to say beyond what I said a minute ago in response to Michael's questions. Again, we view that – ***the outlook for this business is going to continue to be very solid . . . So, yeah, I mean this is the plasma that is going forward is going to continue to be very solid.*** Beyond that to say whether we have upside or downside, I would say we have a balanced projection, so we will leave it at that.

223. Baxter's September 16, 2009 investor conference also marked the first time the Company mentioned the 2010 launch of its next-generation infusion pump and further discussed remediation of the Colleague pump:

> The second bullet speaks to the criticality of launching our next-generation pump platforms over the LRP. I'm pleased to say we're well on our way with the SIGMA International deal we announced in April, which gives Baxter exclusive distribution rights for Spectrum infusion pumps. The introduction of the pump, as well as the development of our next-generation pumps are critical steps in turning this business back into a growth driver.
>
> * * *
>
> ***So COLLEAGUE, COLLEAGUE has been a workhorse pump for nearly 15 years. So it wasn't designed with current generation smart pump features, I mean it has limited communication capabilities unlike our next-generation pumps. However, because of the workflow and ease-of-use, it's still favored by many customers worldwide. And as you know, COLLEAGUE is in the midst of being remediated in the U.S. and we will continue to complete our obligations to customers.*** That being said, as with all older platforms, COLLEAGUE will be phased down in the future and Spectrum and our next-generation pumps will be the platform that we'll base our growth on in the years to come.

224. Further discussing remediation of the Colleague pump, Parkinson stated, in pertinent part:

> ***We have remediated well over 100,000 devices in the U.S. We continue to work with the FDA on how we move forward and complete that remediation.***
>
> ***There has been a number of things that as we have conducted the remediation that was a basis of some follow-on field corrective actions that we announced earlier in the year, that we still need to get, we still need to get tied down, which we're hopeful that we can get that resolved certainly in 2010.***
>
> * * *
>
> ***So the position we are in now, as we want to complete the remediation of COLLEAGUE.*** We want to understand how our promotional efforts focused on COLLEAGUE going forward, SIGMA and our next generation platform recognizing that the response to SIGMA to date has been very good, very good. And we were moving down a path where we were hopeful that we can launch our next generation platform into the U.S. market in the not-too-distant future.
>
> So we are managing all those things. I think that the good news is for the first time in a long time with the SIGMA deal, we are able to proactively promote an infusion

> pump. ***Hospitals continue to hang on to the COLLEAGUES remediated or un-remediated because frankly most of our hospital customers continue to be very satisfied with the product.*** But it is an aging device and at the right time we need to reassess where we allocate our promotional focus in our resources between really now a three, what will be a three-product family.

225. The statements referenced in ¶¶220-24 were each materially false and misleading when made for reasons set forth in ¶202 and the factual details contained throughout this Complaint. In addition, the statements referenced in ¶¶220-24 were materially false and misleading when made because they represented and/or omitted adverse facts which then existed and disclosure of which was necessary to make the statements not false and/or misleading. The true facts, which were known to or recklessly disregarded by each of the Defendants, were:

- Defendants clearly knew that gross margin expansion was not sustainable and that circumstances had changed. By touting a baseless "expectation" of continued margin expansion, Defendants were knowingly misrepresenting the strength of the Company's critical BioScience business.

- Baxter had not successfully remediated 100,000 Colleague pumps. Quite the opposite, rather than fully remediating the Colleague, what "fixes" Baxter did make led to very frequent additional problems and recalls. It was grossly misleading for Defendants to represent to the market that the Company was successfully remediating the Colleague.

- Despite characterizing the Colleague as a "workhorse pump," Defendants knew it remained a violative device at all times during the Class Period. It was beset by many dangerous and life threatening defects that Baxter was incompetent to remediate.

- Rather than being in the "midst of being remediated," the Company's remediation efforts were a disaster. The FDA repeatedly and consistently told Parkinson and Baxter representatives that the Company's remediation efforts were unacceptable and that Baxter's timeline for remediation was far too long. On top of the foregoing, Defendants were well aware of the fact that Baxter did not have a viable Colleague 510(k) submission, remained non-compliant with Part 820, had not begun any Colleague clinical trials, and had not submitted a pre-IDE. Defendants were also well aware that, at a minimum, the Company was several years away from completing Colleague-related clinical trials (assuming the Company received IDE approval from the FDA). Despite Parkinson and Baxter's actual knowledge of each of these facts, Defendants omitted this clearly material information from the market and instead chose to represent that Baxter was looking to conduct the remediation and get it "resolved certainly in 2010."

- Baxter was nowhere near a position of completing remediation of the Colleague. To the contrary, Baxter remained no closer to remediating the Colleague in 2009 or 2010 than it did in 2006. Based on numerous meetings with the FDA, the Company and its representatives, including Parkinson, knew Baxter was not in a position to remediate the Colleague.

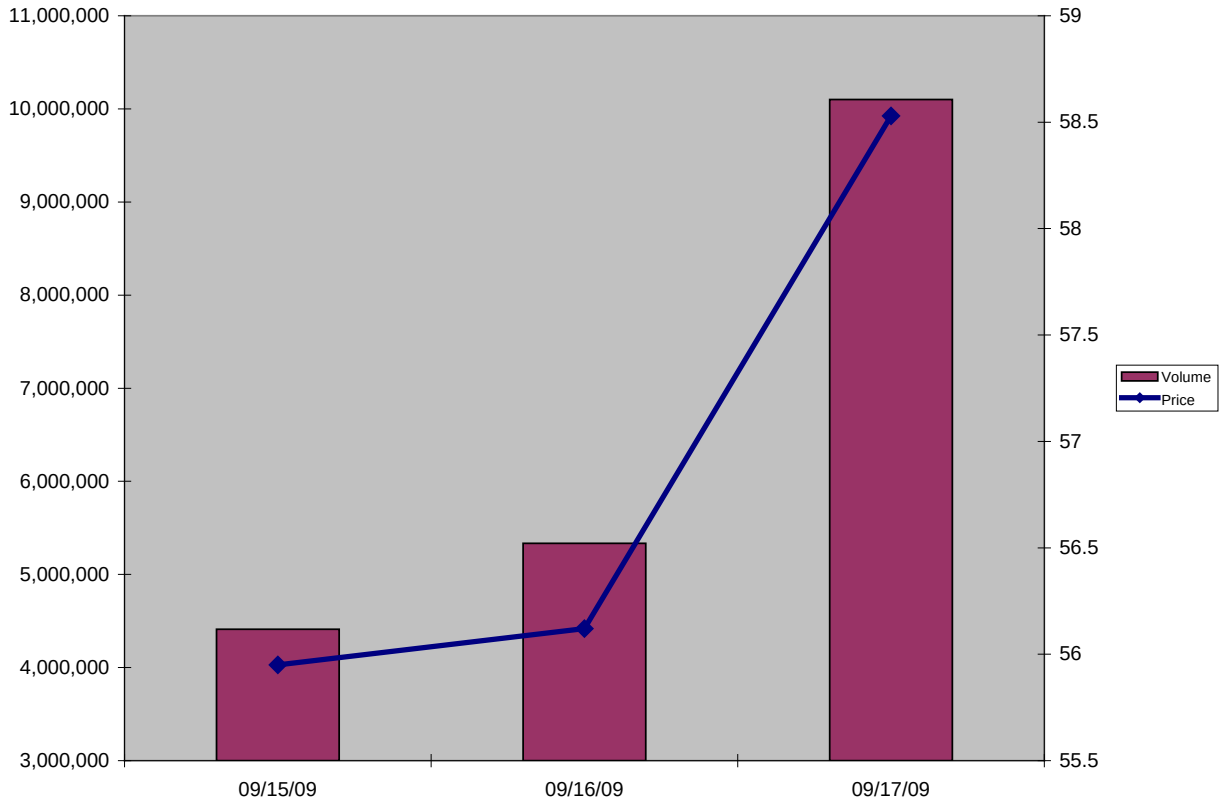
- Defendants were fully aware that Baxter lacked both the capability and the intention of resolving remediation of the Colleague pump in 2010. While Defendants assured the market that Baxter was remediating the Colleague and engaged in an active dialogue with the FDA related to the Company's remediation efforts, Baxter was grossly incapable of (and largely uninterested in) remediating the Colleague.

- Throughout the Class Period, Defendants knew the Company was nowhere near completing its Colleague remediation efforts, and that it was simply not capable of remediating the Colleague in 2010. In fact, it was not until after the September 16, 2009 investor conference that the Company finally committed sufficient resources to remediation, when it hosted the "all hands on deck" meeting in late 2009.

- Defendants knew that any remediation plan the Company submitted to the FDA by late 2009 would rely solely on an unvalidated roadmap, as opposed to completed tests and validated processes. As a result, Defendants knew the Company was, at best, years away from successfully remediating the Colleague, and Defendants' statements to the contrary lacked a reasonable factual basis when made.

- As a result of the foregoing, Defendants lacked a reasonable basis for their positive statements about the Company, revenue projections and financials, as well as its future business prospects.

226. In response to the Defendants' positive statements and outlook, Baxter's common stock rose $2.41 per share, or 4.29%, to close at $58.53 per share on September 17, 2009, on heavy trading volume, as shown in the chart below:



227. On October 15, 2009, Baxter issued a press release reporting the Company's financial results for the third quarter ended September 30, 2009. The Company reported BioScience revenues of $1.4 billion, or a 2% increase over the same quarter in 2008. Baxter also announced its guidance for the fourth quarter 2009 and updated its full-year guidance. The Company stated that "[f]or the Fourth quarter of 2009, Baxter expects sales growth, excluding the impact of foreign currency, of 6 to 8 percent," and Baxter also expected sales growth to increase 7 to 8 percent for the full year.

228. Following issuance of the press release, on October 15, 2009, Baxter hosted a conference call with analysts and investors to discuss the Company's third quarter earnings and operations. Each of the Individual Defendants participated in the call on behalf of the Company. During the conference call, Defendants discussed expected plasma sales growth in the BioScience division and remediation of the Company's Colleague pump. Parkinson spoke positively about the Company's revenue guidance for 2009, stating in pertinent part as follows:

> ***In closing, I would say that building momentum of our pipeline and continuing strong financial results validate the strength of the diversified healthcare model and reflect our ability to achieve the longer-term objectives that we laid out at our investor conference in September. We believe we have established a strong track record of consistently improving our financial profile and executing our strategy, and we are confident in our ability to sustain that in the future.***

229. As the call continued, Davis discussed Baxter's plasma business growth, revealing that sales had declined while emphasizing that demand had not weakened. Davis stated, in pertinent part:

> Moving onto plasma proteins, you may recall that our plasma protein portfolio includes a broad array of propriety and differentiated products including Feiba, an inhibitor therapy; ARALAST, a treatment for hereditary emphysema; and FLEXBUMIN, or albumin provided in a flexible plastic container.
>
> In the third quarter, global plasma protein sales were $331 million and declined by 2%. Excluding the impact of foreign currency, plasma protein sales increased 7%. Last year, significant tenders primarily for Feiba contributed to plasma protein growth of 37%, the highest quarterly growth in 2008. Excluding tenders, the timing of which can be uncertain, plasma protein sales increased by more than 15% including robust sales of albumin and ARALAST, both of which grew in excess of 20% of the quarter.
>
> In addition to a difficult comparison, growth was impacted by a change in the timing of plasma orders primarily in Eastern Europe and Latin America versus our expectations. We now expect these sales in the fourth quarter.
>
> ***To summarize, we continue to see strong demand and favorable year-on-year price improvements across the entire plasma protein portfolio.***
>
> In antibody therapy, sales of $336 million grew 9% and excluding foreign currency, sales advanced 12%. This is the continued result of increased demand and higher year-on-year prices. ***Additionally, we continue to estimate demand growth in high single digits at the high-end of the mid to high single digit longer term guidance we provided at our investor conference last month.***

230. During the question and answer session of the conference call, Davis further discussed the plasma business stating, in pertinent part:

> I would say that ***our guidance we've given previously for the full year for plasma proteins of high teens hasn't changed. So we're still confident we're going to see high teens for the full year on a constant currency basis.***

231. As the call continued, a Morgan Stanley analyst asked defendants to clarify their view on the plasma protein side of the business and whether anything had changed relative to defendants' view of the health of the market or the price of the market. In response, Davis simply said, "***No***." Later in the call, Parkinson reiterated that plasma declines were strictly related to market timing, and that demand had not weakened, stating:

> ***But I would just say add on to that. It purely is timing, Bob. One of the discussions we've had in previous earnings conferences and so on is whether or not given the macroeconomic environment, underlying demand for our products would decrease. Would that manifest itself in parts of the world in terms of fewer tenders or less volume on tenders for plasma proteins and so on? And frankly, we have really seen none of that. It's not like there's tenders that we had last year that aren't recurring this year. So it purely is a timing dimension.***

232. In response to a series of questions regarding plasma collection trends, Davis stated, in relevant part:

> ***We are seeing our collections slow down, and we are trying to be very plentiful in how we manage our overall collection base, both in terms of number of centers, hours the centers are open, fees we pay, any kind of marketing programs we give. So all of those things are items we are looking at to make sure that we are, again, planful in how we approach this.***
>
> ***The end result of that is our collections are down, and as we look forward, it will result in a lower cost to collect.*** I would caution you, though, that to try to translate that into a significant margin benefit, to the extent we slow down collections and as a result slow down fractionation, there is an offsetting loss of throughput variance on our plants.
>
> So as we look at it right now, I don't see it as a material upside or a downside. It kind of is just offsetting what we'll move through our fractionation chain next year.

233. Further, when asked about possible price increases in the antibody business, Parkinson stated, in pertinent part:

> I don't want to get into perspective pricing this morning for reasons you understand, not the least of which is we're in the middle of negotiating contracts with a number of folks and so on. Okay? ***As I stated earlier, our view on this is unchanged from what we've communicated to you previously.***

234. Also during the conference call, a Morgan Stanley analyst commented that, "there's been a lot of kind of consternation around pricing and through the balance of the year," and "Baxter remains extremely well insulated versus some of these macro concerns." The analyst then asked whether Baxter was concerned about new competitors entering the US market for IVIG or for any sort of GPO contracts, and whether the increased competition would effect the Company's market share, Parkinson stated, in relevant part:

> I would say not really. Look, we continue -- one of the things that our improved inventories have allowed us to do is frankly be more proactive in terms of demand creations. We've discussed before PID is still highly underdiagnosed and treated even in developed and mature markets like [the] US and Western Europe. And our improved inventories have enabled us around the world to selectively invest in marketing programs and so on to capitalize on that.
>
> ***So there's no indication at all that certainly that we're losing market share and we don't plan on losing market share.***

235. Later in the call, Parkinson responded to questioning regarding softening of plasma pricing and pricing pressure in Europe, stating in pertinent part:

> [W]e are not going to be specific and comment beyond what we already have in our own pricing. We are certainly not going to comment on the competitors' price, so I'm just going to leave it at that.

236. Also during the call, questions were raised regarding "difficult" year-over-year comparisons on the remediation of the Company's Colleague pump and whether defendants could give an update on Colleague. Parkinson and Ladone responded in pertinent part:

> Parkinson: It will continue in Q4, probably not to the same degree because it was like midyear last year if I recall, Mary Kay, correct me but we really had the peak remediation revenue because of the cycle. It started to flatten off later in the year.
>
> Ladone: Q3 was really a difficult comp, Ben. And Q4, we should see growth probably more in the mid-single digit range. . . Yes, set growth I would say generally was pretty flat. It was a little down in the quarter, but it was down by less than $5 million in sales.

237. On October 29, 2009, Baxter filed its quarterly report on Form 10-Q for the quarter ending September 30, 2009, which confirmed the financial results announced in the October 15,

2009 press release and was signed by Davis (the "Third Quarter 10-Q"). The Third Quarter 10-Q contained required Sarbanes-Oxley certifications signed by Davis and Parkinson stating that the Form 10-Q did not include any material misrepresentations. In the Third Quarter 10-Q, Baxter stated:

> ***The company remains in active dialogue with the U.S. Food and Drug Administration (FDA) about various matters with respect to the company's COLLEAGUE infusion pumps, including the company's remediation plan and reviews of the company's facilities, processes and quality controls by the company's outside expert pursuant to the requirements of the company's Consent Decree. The outcome of these discussions with the FDA is uncertain and may impact the nature and timing of the company's actions and decisions with respect to the COLLEAGUE pump.*** The company's estimates of the costs related to these matters are based on the current remediation plan and information currently available. It is possible that substantial additional charges, including significant asset impairments, related to COLLEAGUE may be required in future periods, based on new information, changes in estimates, and modifications to the current remediation plan.
>
> While the company continues to work to resolve the issues associated with COLLEAGUE infusion pumps and its heparin products described below, there can be no assurance that additional costs or civil and criminal penalties will not be incurred, that additional regulatory actions with respect to the company will not occur, that the company will not face civil claims for damages from purchasers or users, that substantial additional charges or significant asset impairments may not be required, that sales of any other product may not be adversely affected, or that additional legislation or regulation will not be introduced that may adversely affect the company's operations and consolidated financial statements.
>
> * * *
>
> Partially offsetting this sales growth in both periods was a decline in Infusion Systems sales due to lower revenues from access sets and COLLEAGUE infusion pumps which remain in use ***as the remediation plan is executed***.

238. The statements referenced in ¶¶227-37 were each materially false and misleading when made for reasons set forth in ¶220 and the factual detail contained throughout this Complaint. In addition, the statements referenced in ¶¶227-37 were materially false and misleading when made because they represented and/or omitted adverse facts which then existed and disclosure of which

was necessary to make the statements not false and/or misleading. The true facts, which were known to or recklessly disregarded by each of the Defendants, were:

- Defendants had no reasonable basis for maintaining Baxter's financial guidance for plasma proteins or claiming demand for plasma-derivative products was strong. To the contrary, Defendants knew pricing and sales were softening, that the Company was losing market share, and that it was experiencing erosion in its profit margins. Defendants knew Baxter's margin expansion was not sustainable and would be significantly reduced. The result of the foregoing is that Defendants knew the Company would be unable to meet its long-term objectives.

- As a consequence of decreased sales and the re-emergence of Talecris – which weakened Baxter's stranglehold on supply – Defendants lacked a reasonable basis for claiming there would be "favorable year-on-year price improvements." In reality, Defendants knew that as a result of changed economic circumstances in the marketplace for these products, the Company would be forced to lower prices or sustain substantial market share losses.

- Defendants failed to inform investors that the slowdown in collections of plasma was a direct result of Defendants' ongoing attempt to manipulate the plasma supply. Defendants intentionally reduced blood intake countrywide by lowering donor fees, decreasing the hours of operation, and lowering the marketing budgets for the Company's plasma collection centers. The impact of the Company employing internal levers to manipulate supply was the only thing enabling Defendants to maintain their charade of positive pricing in the plasma-derivative products market.

- By October 2009, Baxter's dialogue with the FDA's Office of Compliance was clearly anything but "active." By the time of the Company's Form 10-Q, the FDA's Office of Compliance had "gone dark" regarding the Colleague. As an experienced medical device manufacturer, Baxter and its representatives were well aware that the Office of Compliance's silence meant that the FDA was considering additional, punitive measures against Baxter pursuant to the terms of the Consent Decree. Indeed, Baxter had repeatedly been told by the FDA that its remediation plans were inadequate.

- While the FDA's Office of Compliance cut off substantive communication with the Company regarding the Colleague pump, Baxter was scrambling to resolve the issues associated with it at the end of 2009. But, Defendants failed to inform the market that Baxter was grossly incapable of remediating the Colleague. Far from being "uncertain," Defendants knew the Company was, at a minimum, several years away from being able to remediate and re-commercialize the Colleague pumps.

- Nearly a full year after the FDA demanded clinical data in support of any Colleague-related 510(k) submission, Baxter still had not received pre-IDE approval and had not begun any clinical trials. As a result, Defendants knew Baxter lacked any verifiable or validated data demonstrating the safety and efficacy of any remediation plans that the Company could propose to the FDA. Despite knowing the FDA would

reject any 510(k) that did not include clinical data, Defendants omitted this material fact from their Class Period statements while simultaneously omitting the fact that the Company was no longer in "active dialogue" with the FDA's Office of Compliance regarding the Colleague.

- As a result of the foregoing, Defendants were fully aware that the Company was in no position to and was wholly incapable of executing any Colleague remediation plan for at least a period of several years, if at all.

- As a result of the foregoing, Defendants lacked a reasonable basis for their positive statements about the Company, revenue projections and financials, as well as its future business prospects.

239. In response to news that plasma sales had abruptly fallen, as well as intense questioning on softening in the plasma market, the price of Baxter common stock fell $2.50 per share, or 4.5%, from a closing price of $57.00 per share on October 14, 2009 to close at $54.50 per share on October 15, 2009, on heavy trading volume. Following the release of the Third Quarter 10-Q, on October 29, 2009, the price of Baxter common stock remained flat. But for Defendants' false and misleading statements the price of Baxter common stock would have fallen further.

240. On November 11, 2009, Davis participated in the Credit Suisse Healthcare Conference on behalf of the Company. During the conference, Davis made several false and misleading statements, including the following:

> If you focus on our first business, which is our largest business, that being bioscience. In 2008 we enjoyed sales of $5.3 billion and this was spread across our recombinant franchises, our plasma proteins, regenerative medicine, and vaccines. As we've talked about at our recent investor conference we had a couple of years ago, ***we do expect to see growth in this business on the top line of 7% to 9% overall long range plan.*** And I'll talk about here in a moment some of the key areas we see, which will really allow us to drive that kind of growth in this business.
>
> * * *
>
> ***Obviously, as we look within the space with the plasma products, our focus continues to be to focus on the needs of our patients and to make sure we drive demand. And while obviously, we want to maintain reasonable inventory levels to make sure we can continue to make sure supply matches that demand, the important point here is to focus on demand growth and why we feel so strongly about the growth that's still out there in demand.***

* * *

So in summary, we feel we are very well positioned. Our diversified model, our global reach, the medically necessary nature of our products puts us in a very good position to deal with a changing macro environment, whether it be the economic changing conditions we see or the changing conditions we're probably going to experience as we continue to look at healthcare reform in the United States.

While no company is immune from this, we think we are very well positioned to continue to deliver the kind of growth we've given you in the past and we've outlined here today. And really, as we've said in the past, it's not about us trying to find those avenues of growth. They're there. We know what they are.

It's really now just a matter of us executing on those opportunities. And we think we will obviously be able to do that and deliver the results you've come to expect from us, and continue to grow this business.

241. On January 12, 2010, Davis participated in the JP Morgan Healthcare Conference on behalf of the Company. During the conference, Davis misled the market, and stated, in pertinent part:

Now turning to the businesses, and I'll go in depth in each of the businesses in a little bit, BioScience is our largest business with sales in 2008 of $5.3 billion. ***And as you look out over our long-range horizon, we do expect the BioScience business to continue to grow in the 7% to 9% on a compounded average basis.***

* * *

Another key franchise for the Company is our plasma biotherapeutics business. And as you can see here from the chart, ***we continue to believe we are going to see strong growth in demand in this business.*** And I would comment up front that as we look at a lot of noise we've heard recently on people focusing on the quarter-to-quarter moves in this business, ***I would take you back to the detailed presentation we gave in September and tell you that our outlook for the long-term of this business with growth in demand in the mid-to high-single digits has not changed.***

* * *

So for us it is about what we look forward for the sustainability of this business and making sure we're in a position to continue to be able to deliver product to meet a growing demand long-term in the marketplace.

* * *

So as we look at this business, ***we continue to have confidence in it, we continue to see it as a sustainable growth business for the Company and one which will continue to drive value for the Company.***

* * *

> So as you look at the culmination of all of those businesses and as we look out over our long-range plan, ***we do believe we are going to be able to deliver sales growth in the 7% to 8% range with gross margins approaching 55%***, operating margins around 28%, and you can see EPS in the 11% to 13%. So we will continue to be able to drive good leverage of our sales line into our EPS and, obviously, continue to generate very strong cash flow.
>
> Obviously, ***a key part of our story over the last couple of years has been our ability to drive gross margin expansion. And I will tell you that we will continue to do this into the future.*** And as you look at the drivers of what will allow us to do that, it's largely the same drivers we've had today. It's going to be mix upgrades, first, at the highest level, with business mix driving margin expansion with bioscience being our highest-margin business, also the fastest-growing business, as well as product upgrades within each of the businesses. So you are going to get mix at a different level. And between, really, those two areas, that will be the majority of what will drive margin expansion into the future to that 55% range I mentioned, and has been, frankly, what has driven it up to this point, more so than I think most people understand.

242. The statements referenced in ¶¶240-41 were each materially false and misleading when made for reasons set forth in ¶202 and the factual detail contained throughout this Complaint. In addition, the statements referenced in ¶¶240-41 were materially false and misleading when made because they represented and/or omitted adverse facts which then existed and disclosure of which was necessary to make the statements not false and/or misleading. The true facts, which were known to or recklessly disregarded by each of the Defendants, were:

- Defendants had no reasonable basis for repeatedly assuring investors Baxter would continue to see growth in its BioScience business as well as growth in demand and gross margin expansion. Further, Defendants knew Baxter was not "very well positioned to continue to deliver the kind of growth we've given you in the past…." Defendants knew the Company's past ability to manipulate supply and maintain price control was the basis for Baxter's prior growth and was imperative to its future financial growth, but that the Company had lost its ability to maintain such iron-fisted control over the plasma-derivative products market due to the collapse of the CSL-Talecris merger.

- Although Baxter was taking steps to manipulate blood plasma supply, such as intentionally reducing blood intake countrywide, lowering donor fees, decreasing the hours of operation and lowering the marketing budgets for the Company's plasma collection centers, Defendants knew Baxter would not be able to maintain its sales growth and would instead face loss in its market share and margins.

- Baxter failed to inform the market that its ability to "make sure supply matches demand" was based on the carefully orchestrated (and crumbling) anticompetitive cartel it created with CSL.

- It was not the Company's "life-saving" products that insulated the Company from the overall macro environment; rather, it had been the Company's carefully orchestrated scheme to manipulate prices and supply that stabilized the Company's financial performance.

- As a result of the foregoing, Defendants lacked a reasonable basis for their positive statements about the Company, revenue projections and financials, as well as its future business prospects.

243. On January 14, 2010, Morgan Keegan upgraded Baxter to "Outperform," "based on field checks at 55 plasma collection centers." According to a survey by analysts at Morgan Keegan, "plasma collection is being actively managed by the biologics companies." The analyst report further stated, in part:

> We upgrade the shares following our plasma survey, FCF acceleration, and the optionality of the pipeline. Our upgrade of Baxter shares is predicated on the following: (1) The company remains a strong competitor in the IVIG market, which we expect to grow in the mid-high single-digit range over the next several years. Specifically, we assume that demand is likely to grow 5%-8% in the current economic environment with the potential for 0%-2% price increases. Importantly, we do not see IVIG sales growth going negative in 2010 as many investors fear. Looking forward, as the economic environment improves and unemployment rates decline, we believe that demand growth for IVIG could move back towards the 8%-10% rate. However, at this point, we have not assumed any rebound in our model. (2) We anticipate a double-digit acceleration in free cash flow generation in 2010 and 2011 as capital spending peaks. (3) Over the next several years, we like the optionality in Baxter's R&D pipeline, including IVIG in Alzheimer's, subcutaneous administration of IVIG, vaccines, and the company's stem cell projects. (4) We expect the company to grow earnings at the mid-upper end of its projected 11%-13% range in 2010, which appears to be attractive when compared to other large-cap diversified healthcare companies. Moreover, Baxter's portfolio of medically-necessary products reduces the risk in a healthcare reform environment, and continues to provide international expansion opportunities. (5) Baxter's balance sheet remains strong with $2.6 billion in cash and a debt-to-total-capital ratio of 10%. Given the company's financial strength, we would anticipate that Baxter could get more active in acquisition activity in 2010, which we believe would be a positive for the shares.

244. On January 19, 2010, Baxter was downgraded from Buy to Hold by Citigroup as a result of the plasma sales slowdown in the Company's BioScience division.

245. On January 25, 2010, Crain Communications published an article entitled, "Baxter plasma biz has its hospital customers seeing red; Lawsuits allege 'cartel' controls price in drug firm's key division," discussing how at least seventeen hospitals have sued Baxter since last summer. The lawsuits contend that Baxter is involved in a "conspiracy with competitors to operate a 'cartel' that controls prices for therapies made from human plasma."

246. On January 28, 2010, Baxter issued a press release reporting the Company's financial results for the full-year and fourth quarter of 2009. The Company reported BioScience revenue of $1.5 billion for the first quarter. The press release further provided, in pertinent part:

> "In 2009, Baxter achieved record financial results and enhanced shareholder returns," said Robert L. Parkinson, Jr., chairman and chief executive officer. "Each of our businesses and regions contributed to our strong financial performance in the fourth quarter and for the full year, which reinforces the value of the diversified business model, the medically-necessary nature of the portfolio, and our strong global presence."
>
> * * *
>
> Baxter also announced today its guidance for the full year and first quarter of 2010. ***For full-year 2010, Baxter expects sales, excluding the impact of foreign exchange, to grow 5 to 7 percent.*** Including the benefit of foreign exchange, Baxter expects reported sales growth to increase 7 to 9 percent compared to 2009, based on current exchange rates. ***The company also expects earnings per diluted share of $4.20 to $4.28, before any special items, and expects to generate cash flow from operations of approximately $2.9 billion.***
>
> ***For the first quarter of 2010, Baxter expects sales growth, excluding the impact of foreign exchange, of approximately 5 to 7 percent. Including the benefit of foreign exchange, the company expects reported sales growth of approximately 10 to 12 percent compared to the first quarter of 2009, based on current exchange rates. The company also expects earnings per diluted share of $0.92 to $0.94, before any special items.***
>
> ***"Our 2010 guidance reflects balance across the businesses, continued global expansion, and our ability to deliver sustainable growth,"*** said Robert M. Davis, corporate vice president and chief financial officer. "It is aligned with our long-range strategic and financial objectives, as we remain focused on delivering growth while making appropriate investments for the future."

247. The January 28, 2010 press release also revealed that within the United States, Baxter's sales in its plasma protein business increased by only 3% in the fourth quarter of 2009 as compared to the fourth quarter of 2008.

248. Following issuance of the press release, on January 28, 2010, Baxter hosted a conference call with analysts and investors to discuss the Company's full-year and fourth quarter earnings and operations. Each of the Individual Defendants participated in the call on behalf of the Company. During the conference call Defendants discussed expected plasma sales growth in the BioScience division and remediation of the Company's Colleague pump. For example, Davis further discussed Baxter's BioScience division, stating in pertinent part:

> For the full-year plasma protein sales totaled $1.3 billion and increased 17% on a constant currency basis ***as a result of strong underlying global demand and favorable year-on-year price improvements across the entire plasma protein portfolio.***
>
> In antibody therapy fourth-quarter sales of $351 million advanced 14% and, excluding foreign currency, sales increased 10% and were significantly impacted by strong demand outside the US. ***Antibody therapy sales in the US increased 4% due to a number of factors including somewhat lower market growth resulting from general macroeconomic conditions, inventory adjustments in the channel and some modest share loss.***
>
> ***For the full year antibody therapy sales totaled $1.4 billion and increased 14% on a constant currency basis driven by higher global demand and year-on-year price increases. I'd mention that we remain confident in the underlying fundamentals of this business*** and have not changed our outlook of mid- to high-single-digit growth in demand over our LRP.
>
> * * *
>
> Finally, for the BioScience business ***we expect sales growth, excluding foreign currency, to be in the 6% to 8% range.*** First, we expect recombinant sales growth in the 6% to 8% range. Second, ***we expect plasma protein sales to grow in mid- to high-single-digits, and antibody therapy sales to grow in the mid-single-digit range.*** Third, we expect the regenerative medicine business to again grow in mid teens.
>
> * * *

> For the first quarter, as we mentioned in our press release, we expect earnings per diluted share of $0.92 to $0.94 and sales growth, excluding the impact of foreign currency, of 5% to 7%.

249. Discussing the Company 2010 outlook, Parkinson added, in part:

> Clearly 2009 was a very successful year financially, operationally and strategically. While we're certainly not without challenges, ***we believe our company is very well positioned for 2010 and beyond. While no company, including Baxter, is completely immune to the macroenvironment, given the medically necessary nature of our products, our diversified healthcare model and strong market positions we're confident in our ability to drive improved performance.***
>
> ***Our 2010 outlook is aligned with our long-range strategic plans and the solid underlying fundamentals we see in the markets in which we operate.*** And we remain committed to driving growth while investing in innovation and business development activities that position us for enhanced growth in the future.

250. During the question and answer portion of the January 28, 2010 conference call, Parkinson further discussed the Company's long-term guidance, stating in pertinent part:

> ***Well, first of all it's only been what, four months since our investor conference, but there's nothing that's changed since then that would suggest we would deviate from our long-term outlook, long-term aspirations. Obviously the guidance we provide of EPS growth in 2010 is right in line with the 11% to 13% compounded EPS growth that we projected over the LRP.***
>
> ***So in the context of EPS growth, 2010 is just another year that I think supports and builds that long-term outlook.*** You've got a few puts and takes relative to the sales line in organic growth. And just to remind you and I think everyone else, the organic sales growth that -- or the sales growth, compounded sales growth that we projected really doesn't reflect much of anything in terms of business development initiatives and so on.
>
> So we're hopeful that we'll be in a position to maybe do a few things this year as well that will support that top line. But, the ***EPS growth that we're guiding for 2010 is right in line with the messaging for the long-range plan we communicated in September.***

251. As the call continued, Parkinson responded to a question from a Morgan Keegan analyst regarding IVIG growth, pricing, and market share, and stated, in pertinent part:

> Let me start with our long-term outlook for this business. ***We continue to believe what we communicated at the investor conference in terms of the long-term growth of this business is very much intact.***

Relative to pricing I want to be limited in what I say. I mean, clearly pricing in the market right now is reasonably flat. Going forward I don't really want to comment on that given some of the situations that you're familiar with that have transpired. So I won't embellish beyond that in terms of price.

In terms of volume, without getting too detailed, 2009, particularly the second half of the year, there's really been kind of a confluence of events that have gone on I think affecting both market volume and then also ours, which gets to your share question which I'll conclude with.

First of all, I do think there's been some modest softening in the underlying demand of the entire market due to the macroeconomic environment. While largely Baxter has been fortunate to be relatively unimpacted by the macroenvironment, I do think given how expensive this therapy is, individuals losing insurance, some things like that, I think it has had somewhat of a softening effect in terms of the underlying market growth in 2009.

We also had the dynamic, as you know, earlier in the year with one of the major competitors going private to become a public company. There are always dimensions that are associated with that kind of an event which complicate the market. I also think throughout the year there's been a balancing of the channel inventory with underlying demand, which I think as we go out the year has probably worked its way -- worked its way through.

The other thing I would point out, particularly in our case where we took a fairly significant price increase in January in 2009, in anticipation of that there was a bit of a pre-buy I think from wholesalers to avoid the price increase late in 2008, which clearly didn't occur this year. So on a year-to-year comp basis that's had a bit of a downward effect.

And then finally in the last point, yes, ***I think we probably have lost a little bit of share. I don't think it's significant. And frankly, to the degree we have, it's probably share that we gained in '08 and moving in -- even early into '09. I don't think there's any reason to believe that that's going to change much going forward. But I think the second half of the year we probably did lose back some of the share gain that we enjoyed in '08 and early '09.***

So I'll stop there. I covered a lot of dynamics, but I think it's fair to say 2009 was kind of a transition year due to a lot of different dynamics. But again, ***the long-term prospects for this business continue to be very positive for a lot of reasons, not the least of which is antibody therapy has such a robust new product pipeline for us with the label expansion and new indications and new delivery systems and so on. So our long-term view continues to be very positive about this business.***

252. Later in the call, Davis commented on antibody therapy growth, stating in pertinent part:

> [. . .]Bob mentioned we saw maybe a little bit of softness in demand coming through the back half. I think we're seeing some of that recover even as we see data now. But to make sure we're conservative we're looking at the market more in that range. ***But I think longer-term we haven't changed our view that the mid- to high-single-digit growth, it's going to get there and I wouldn't be surprised if you see us getting back to that as we move into the rest of 2010 in the back half.***

253. As the call continued, a Morgan Stanley analyst questioned whether Baxter's 2010 guidance was predicated on stable market share, whether guidance was further predicated on inventory levels being flat when compared to the fourth quarter of 2009, and what gave the Company confidence that there would not be further market share and inventory level losses in 2010. Davis responded in pertinent part:

> ***The answer to both the questions is, yes, we are assuming generally stable share throughout 2010.*** As Bob mentioned***. Some of the share loss we think we've seen in the back half of 2009 is giving back share gains we had in the past years. As you know, there were competitive issues with the product in the marketplace.***
>
> ***So, we do expect stable share and we do believe that we're starting to see more normalized inventory levels in the channel. So hopefully some of the noise that's created in the back half of 2009 versus 2010, we're not expecting to see that within the -- back half of 2009 versus the first half of 2009 -- sorry about that. But we're not expecting to see that in 2010.***

254. Near the end of the call, an analyst from William Blair questioned, "And on your guidance for Med Delivery, what are you baking in for timing of full return to the US of Colleague?" In response, Davis misleadingly stated "[w]e're assuming no Colleague sales in 2010."

255. Also on January 28, 2010, *Reuters Limited*, published an article discussing Baxter's financial results. The article cited, the $1.18 price decline as the result of the Company acknowledging that "it lost some share in the market for plasma proteins last quarter."

256. On February 19, 2010, Baxter filed with the SEC its Annual Report on Form 10-K for the year ending December 31, 2009 (the "2009 10-K"), which confirmed the previously announced financial results and was signed by Parkinson and Davis. The 2009 10-K further stated, in relevant part:

In July 2005, the company stopped shipment of COLLEAGUE infusion pumps in the United States. Following a number of Class I recalls (recalls at the highest priority level for the FDA) relating to the performance of the pumps, as well as the seizure litigation described in Note 11, the company entered into a Consent Decree in June 2006. Additional Class I recalls related to remediation and repair and maintenance activities were addressed by the company in 2007 and 2009. The Consent Decree provides for reviews of the company's facilities, processes and controls by the company's outside expert, followed by the FDA. In December 2007, following the outside expert's review, the FDA conducted inspections and remains in a dialogue with the company. As discussed in Note 11, the company received a subpoena from the Office of the United States Attorney of the Northern District of Illinois relating to the COLLEAGUE infusion pump in September 2009. As discussed in Note 5, the company has recorded a number of charges in connection with its COLLEAGUE infusion pumps. It is possible that substantial additional charges, including significant asset impairments, related to COLLEAGUE may be required in future periods, ***based on new information, changes in estimates, and modifications to the current remediation plan***.

* * *

BioScience Pre-tax income increased 5% in 2009 and 21% in 2008. ***The primary drivers of the increase in pre-tax income in both years were continued gross margin expansion driven by strong sales of higher-margin products, fueled principally by the continued customer adoption of ADVATE therapy and increased demand and improved pricing for GAMMAGARD LIQUID therapy and certain other plasma protein products, as well as continued manufacturing improvements.*** Partially offsetting the growth in both years was increased R&D spending and, in 2009, the unfavorable impact of lower FSME-IMMUN vaccine sales. Foreign currency had an unfavorable impact on 2009 growth and a favorable impact on 2008 growth.

* * *

Infusion Pump Charges

The company remains in active dialogue with the FDA regarding various matters with respect to the company's COLLEAGUE infusion pumps, including the company's remediation plan and reviews of the company's facilities, processes and quality controls by the company's outside expert pursuant to the requirements of the company's Consent Decree. The outcome of these discussions with the FDA is uncertain and may impact the nature and timing of the company's actions and decisions with respect to the COLLEAGUE pump. The company's estimates of the costs related to these matters are based on the current remediation plan and information currently available. It is possible that substantial additional charges, including significant asset impairments, related to COLLEAGUE may be required in future periods, based on new information, changes in estimates, and modifications to the current remediation plan.

> While the company continues to work to resolve the issues associated with COLLEAGUE infusion pumps, there can be no assurance that additional costs or civil and criminal penalties will not be incurred, that additional regulatory actions with respect to the company will not occur, that the company will not face civil claims for damages from purchasers or users, that substantial additional charges or significant asset impairments may not be required, that sales of any other product may not be adversely affected, or that additional legislation or regulation will not be introduced that may adversely affect the company's operations and consolidated financial statements.

257. Between the Company's January 28, 2010 press release and conference call and the filing of its 2009 10-K on February 19, 2010, the price of Baxter common stock traded flat between the range of $56.01 and $58.02. But for Defendants' false and misleading statements the price of Baxter common stock would have fallen further.

258. The statements referenced in ¶¶246-54, 256 were each materially false and misleading when made for reasons set forth in ¶202 and the factual detail contained throughout this Complaint. In addition, the statements referenced in ¶¶246-54, 256 were materially false and misleading when made because they represented and/or omitted adverse facts which then existed and disclosure of which was necessary to make the statements not false and/or misleading. The true facts, which were known to or recklessly disregarded by each of the Defendants, were:

- The Company's loss of market share was significant and gave Defendants no reasonable basis for "assuming generally stable share throughout 2010." In fact, by January 2010, Morgan Stanley recognized in a research report that "[s]hare volatility is increasing and has favored Talecris and CSL at Baxter's expense in the hospital segment of the market, which represents roughly 50% of the total market." Despite this, Defendants materially misled investors and the market by maintaining the Company's earlier financial guidance and stating that the "long-term growth of this business is very much intact."

- Although Defendants admitted the Company had "lost a little bit of share," they misleadingly downplayed its significance. Defendants were fully aware the Company's market shares losses stemmed from Baxter's inability to control prices, manipulate supply, and artificially inflate its gross margins. By deliberately downplaying any loss of share, by predicting "stable share" in 2010, and by hiding the true reasons for loss of share, Defendants further misled the market.

- Although Defendants were correct in telling the market Baxter expected no Colleague sales in 2010, they neglected to tell investors that the Company remained

years away demonstrating any verifiable and validated clinical data that was required by the FDA prior to the Company being able to successfully remediate the more than 200,000 Colleague devices in use in the United States.

- By February 19, 2010, Baxter had not been in active dialogue with the FDA's Office of Compliance regarding the Colleague for approximately four months. Defendants were well aware that the ongoing lack of communication was a clear signal to Baxter that the FDA was considering and implementing punitive actions against the Company for its ongoing failure to remediate the Colleague consistent with the terms of the Consent Decree.

- Although the Company represented that it had a remediation plan, the reality was that it simply did not. Any plan submitted by the Company to the FDA had been rejected, and at the time of Defendants' statements, the Company did not have a 510(k) submission, did not have any clinical data, and did not even have IDE authorization to conduct a clinical trial. Thus, whatever remediation "plan" Defendants were referring to was merely hypothetical.

- Because the Company was not capable of working to resolve the issues surrounding the Colleague, and because the FDA's Office of Compliance had cut off substantive communications with the Company regarding the Colleague, Defendants misled the market by omitting material, then-known information from Baxter's so-called risk warnings.

- As a result of the foregoing, Defendants lacked a reasonable basis for their positive statements about the Company, revenue projections and financials, as well as its future business prospects.

259. On March 3, 2010, Davis and Ladone participated in the RBC Capital Markets Healthcare Conference on behalf of the Company. During the question and answer portion of the conference, Davis was asked about the "hot button topic" over the last nine months, the Company's BioScience business. More specifically, Davis was asked about investor focus on the plasma-derived pharmaceutical business, in addition to IVIG, and concerns about volume and price. In response, Davis stated in part:

> Yes, yes. So, and I'll focus on IVIG specifically, antibiotic therapy, because I think that's really what most people are curious about. As you look at 2009 and what played out, through the first half of 2009 our growth was faster. You saw it decline as we went into the back half of the year. And a lot of what's going on there I think we talked about even when we had our earnings call for the fourth quarter, but just we can go run back through it again to help everyone out.

If you look at really the dynamics in the marketplace I would start high level by saying we are continuing in a transition period as we really are moving from a market that was constrained to one that's in balance. And as a result, what you did see, one of the factors driving the quarter-to-quarter shifts in 2009 was a burn down of destocking in the channel of inventory that affected us from the first half to the second half.

And you saw that in the data, you see that in the PPTA data. I would remind you that that data is financial data; that's sales into the wholesaler, so that's not necessarily reflective of true demand. And while we did see true demand soften a little bit, it clearly did not reflect what you saw in the PPTA data. And that was really the noise created by what was happening in the channel.

Combined with that there was a lot of activity with competitors. As you know, in the past we've had some competitors who had some supply issues and as a result we did have the opportunity in the first half of 2009, really the back half of 2008, to take some share. I would tell you we probably also gave a little bit of that back in the back half of 2009. And clearly the dynamics with the failed takeover of Talecris and then the subsequent IPO of Talecris, all of that also created noise.

* * *

So a lot of dynamics all working together. I think as we've often said, I would take you back to the bigger picture and say ***from a long-term view of what we gave of a view of this market thinking this is a market that can see mid to high single digit volume growth long-term driven by continued strength in growth and demand and all of the efforts we are putting around increasing awareness, driving access and education -- our view of that market hasn't changed.***

So our confidence that this is a long-term sustainable market for the Company hasn't changed. It's based on the demographics we see, it's based on what we see as an opportunity, as Bob Parkinson has often said, to invest in driving awareness, driving this education really for the first time that we've had an enough product to be able to do that and start to see the benefits of that. Combined with what we see as a very rich new product pipeline for us in this space.

So all those things cause us to still feel very good about this business. And I would caution everyone not to look to the quarter-to-quarter shifts, because there's just so much going on it can create a lot of noise that I think can create panic that maybe isn't necessarily warranted.

260. In response to a question regarding the plasma market and whether Baxter and its competitors were "acting more rational with respect to production end pricing," Davis stated:

Yes, I would focus on Baxter and say we are very committed to making sure we can deliver therapy for patients when they need it as they need it. We're going to drive awareness, drive education. And if we do that we should the able to drive demand

and that will pull the market. And I'll let the competitors -- you can assess that yourself.

261. In response to the March 3, 2010 conference, the price of Baxter common stock remained relatively flat, closing at $59.00 on March 3, 2010, a mere 0.94% increase from the previous trading day. But for defendants' false and misleading statements the price of Baxter common stock would have fallen further.

262. The statements referenced in ¶¶259-60 were each materially false and misleading when made for reasons set forth in ¶202 and the factual detail contained throughout this Complaint. In addition, the statements referenced in ¶¶259-60 were materially false and misleading when made because they represented and/or omitted adverse facts which then existed and disclosure of which was necessary to make the statements not false and/or misleading. The true facts, which were known to or recklessly disregarded by each of the Defendants, were:

- Defendants misled the market by feigning confidence in the plasma-derivative products business and claiming the business would continue to see expanding growth and demand. Defendants knew Baxter had lost significant market share as a result of the competition it was now facing from Talecris, and that such competition spelled doom to its ability to successfully manipulate the plasma market, expand gross margins, and report positive financial results.

- As a result of the foregoing, Defendants lacked a reasonable basis for their positive statements about the Company, revenue projections and financials, as well as its future business prospects.

263. On April 22, 2010, Baxter issued a press release reporting the Company's financial results for the first quarter of 2010. Surprisingly, the Company lowered its full-year 2010 outlook. The press release, stated, in part:

> By business, BioScience revenues totaled $1.4 billion and advanced 9 percent (and excluding foreign currency, BioScience sales increased 3 percent) as a result of continued growth of recombinant therapies, such as ADVATE [Antihemophilic Factor (Recombinant), Plasma/Albumin-Free Method] for the treatment of hemophilia, biosurgery products and shipments of CELVAPAN, the company's H1N1 pandemic vaccine. This performance was partially offset by an increase in Medicaid rebates required by manufacturers of drugs and biologics under the new

U.S. healthcare reform legislation, as well as *weaker sales of antibody therapies and certain plasma proteins.*

* * *

Second Quarter and Full-Year 2010 Outlook

Baxter also announced today its guidance for the second quarter of 2010 and lowered its guidance for the full year.

Previously, Baxter expected full-year 2010 sales growth, excluding the impact of foreign exchange, of 5 to 7 percent (or 7 to 9 percent including foreign exchange); *full-year earnings per diluted share of $4.20 to $4.28, before any special items;* and cash flow from operations of approximately $2.9 billion.

For full-year 2010, Baxter's revised outlook includes sales growth, excluding the impact of foreign exchange, of 1 to 3 percent (or 3 to 5 percent including the benefit of foreign exchange) *and earnings, before any special items, of $3.92 to $4.00 per diluted share.* This outlook now includes the full-year impact of U.S. healthcare reform legislation enacted in the first quarter. In addition, Baxter now expects to generate cash flows from operations of approximately $2.7 billion.

"Our revised financial guidance primarily reflects the impact of recent healthcare reform legislation in the U.S. and our outlook for continued plasma market pressures," explained Robert M. Davis, chief financial officer. "Despite these factors, we will continue to pursue opportunities to enhance growth through the development of new products and business development initiatives, while maintaining an intense focus on managing costs throughout the company."

For the second quarter of 2010, the company expects sales growth, excluding the impact of foreign exchange, of 0 to 2 percent (or 3 to 5 percent including the benefit of foreign exchange), and earnings, before any special items, of $0.90 to $0.93 per diluted share.

264. Following issuance of the press release, on April 22, 2010, Baxter hosted a conference call with analysts and investors to discuss the Company's first quarter earnings and operations. Defendants Parkinson and Davis participated in the call. During the conference call defendants discussed the Company's revised guidance and changes to the global plasma protein market. For example, Parkinson stated as follows regarding the Company's lowered outlook:

There is really primarily two key factors that led us to lowering our outlook for the year. The first, of course, is the incorporation of our best estimates for the recent healthcare legislation on the Company for the remainder of the year. This is largely the impact -- and this is primarily in our BioScience business -- of increased

Medicaid rebates and also the expansion of the 340B program, which provides access to Medicaid rebates in the form of discounts to certain providers.

So we estimate the total healthcare reform impact for 2010 to be approximately $80 million, which is about $0.10 per share.

The second factor is really I guess what I would describe as the more protracted and pronounced impact of the transition in the global plasma protein market, particularly with the emphasis in the US. We will clearly discuss this in more detail in the Q&A this morning, but what I'd like to do is provide some color as it relates to the existing market dynamics, the basis of our projections for the remainder of the year, but also our longer-term view regarding this business.

In the short term, *it is evident that the market is growing more slowly than our earlier estimates, particularly in the US. As I commented last quarter, we also believe that we've lost some unit share, primarily business that we gained in late 2008 or early 2009 due to some competitive supply issues.*

As you know, we've not taken prices up this year on Gammagard Liquid, but it remains the premium brand and is frankly subject to some competitive vulnerability, particularly in select segments of the market. So as a result, we have and we will, on a targeted basis, selectively touch up prices.

While I continue to believe that we and the market more broadly are going through a transitionary period, we, *in retrospect, were clearly overly optimistic about the short-term market growth, our ability to retain market share and the near-term impact on the market of deploying additional sales resources for those indications that remain underdiagnosed and untreated.*

Despite our positive outlook on the growth of the business over the LRP, for the reasons mentioned, we felt it was prudent to adjust down our projections for the remainder of 2010.

265. Discussing the Company's financial performance, Davis stated, in pertinent part:

Sales growth in the US was 4%. International sales increased 17% on a reported basis, and excluding foreign currency, sales growth was 5%.

In terms of individual business performance, let me start with BioScience. Global sales in the first quarter totaled approximately $1.4 billion, and increased 9%. Excluding foreign currency, BioScience sales increased 3%. Overall, strong growth in recombinants, regenerative medicine and vaccines offset weak sales of antibody therapies and plasma proteins.

* * *

Moving on to plasma proteins, which includes a broad array of products, including FEIBA, an inhibitor therapy, ARALAST, a treatment for hereditary emphysema,

FLEXBUMIN, or albumin provided in a flexible plastic container, as well as plasma-derived factor VIII and traditional albumin.

In the first quarter, global plasma protein sales were $292 million and increased by 7%. *Excluding the impact of foreign currency, plasma protein sales declined 1%, as lower albumin and PD factor VIII sales more than offset double-digit growth of FEIBA and ARALAST.*

In the US, plasma sales declined 4%, as growth of ARALAST, plasma-derived factor VIII and FEIBA were more than offset by lower sales of albumin, where we faced a difficult comparison to last year, when US albumin growth was approximately 40%.

International sales, excluding foreign currency, were flat to last year, as double-digit growth of FEIBA offset lower sales of PD factor VIII and albumin, resulting from lost or delayed tenders.

In antibody therapy, sales of $322 million were down by 4%, and excluding foreign currency, sales declined 7%. As we mentioned last quarter, we faced a difficult year-over-year comparison in the first quarter, as antibody therapy sales increased by approximately 20% last year. *In addition to the difficult comparison, however, sales were lower than our expectations due to a number of factors, including somewhat lower market growth, continued inventory adjustments in the channel and continued share erosion.*

266. Davis further discussed Baxter's updated guidance and the impact of pending healthcare legislation on the BioScience division, stating in part:

First, for the full year 2010, as you saw in the press release, we now expect earnings per diluted share of $3.92 to $4.00 compared to our original guidance of $4.20 to $4.28. As Bob mentioned earlier, our revised guidance now includes the impact of US healthcare legislation, which is estimated to be approximately $80 million for the full year 2010, or $0.10 per diluted share.

The majority of this impact is in the BioScience business and relates to the increase in Medicaid rebates in our hemophilia and plasma businesses, as well as new discounts offered to covered entities of the 340B program, which under the new legislation, is being expanded.

In addition to this impact of healthcare reform, *our revised guidance also reflects our current outlook for BioScience, with the major driver being the adjustment of our plasma protein business.* But before I walk you through the sales guidance by business, let me take a moment to summarize our revised guidance by line item of the P&L.

First, we expect full-year sales growth, excluding the impact of foreign currency, of 1% to 3%. *The reduction in our sales is primarily the result of the two factors mentioned earlier, healthcare reform and lower sales of plasma proteins.* Excluding

these factors, our sales guidance would have been within our previous guidance range.

In addition, based on current foreign exchange rate outlooks, we expect our full-year reported sales growth of 3% to 5%. Obviously, the foreign-currency benefit on the sales will be greater in the first half of 2010 versus the second half of the year.

For the full year, we now expect gross profit as a percentage of sales to decline 100 to 150 basis points from the 2009 gross margin rate of 52.4%, primarily resulting from the specific items noted earlier and the ongoing impact of healthcare reform. Given our sales and margin outlook, we will intensify our focus on managing costs throughout the Company. Therefore, we now expect SG&A and R&D to be flat to 2009 levels.

* * *

Now, to expand on the sales assumptions for each of the three businesses. First, as Bob mentioned earlier, we are encouraged by the results in Renal and Medication Delivery, and we continue to expect both businesses to perform in line with our original sales expectations of mid-single-digit growth. *For BioScience, we now expect sales growth, excluding foreign currency, to be flat to down 2%.*

By product category, our revised guidance reflects the impact of healthcare reform and additional sales of approximately $60 million related to the acquisition of ApaTech.

For the recombinant business, we now expect recombinant sales growth in the 4% to 5% range. *Second, we expect plasma protein sales to decline in mid-single digits and antibody therapy sales to decline in the 10% to 15% range.* Third, we expect the regenerative medicine business to have sales growth exceeding 25%, reflecting the ApaTech acquisition and continued double-digit growth in the base business. And finally, we expect the Other category to decline by approximately 5% due to a more conservative outlook of lower advance purchase revenues now that the H1N1 pandemic has subsided.

For the second quarter, as we mentioned in our press release, we expect earnings per diluted share of $0.90 to $0.93, and sales growth, excluding the impact of foreign currency, of 0 to 2%. Based on current foreign exchange rates, we expect reported sales growth of approximately 3% to 5%.

267. Parkinson expanded on the discussion of the Company's revised financial outlook, stating in pertinent part:

Our revised outlook for the plasma protein business would also need to be adjusted in the LRP. Now, while as we said and you know, this business is going to grow nicely for us over the long term, the short-term base, which is really this year and into 2011, will need to be down-adjusted in our five-year projection. So the real question is how long will it take to rebase for us to feel the effect of various

> commercial strategies that we've implemented and will implement going forward, and then of course, get back to a position where we are accelerating growth. That is a question, frankly, I can't answer at this point. But we hope to be in a better position to provide more definition on that as the year progresses.

268. During the question and answer portion of the April 22, 2010 conference call, a JP Morgan analyst questioned why Baxter's outlook changed so "meaningfully." Parkinson responded, in pertinent part:

> *But just on the last point, in terms of the flow-through on profitability, clearly as the volume declines, this is a business where manufacturing efficiencies, plant utilization, both on the collection side as well as on the fractionation side, are real critical*. So as the volumes decline, there is an additional leverage effect that translates into margin that I think probably represents a pretty big piece as you try to reconcile the numbers. So let me just address that at the outset.
>
> But let's take a step back and talk about the market, how we've gotten to this point, what we see going forward. ***Look, the facts are we miscalled this. Okay?*** And believe me, we've spent a lot of time challenging ourselves, asking the question why is that.
>
> I think there are several factors that are involved here, which are instructive and helpful that obviously as we not only forecast going forward, but as we implement other commercial strategies, not only to mitigate the effect of it, but to turn it around.
>
> *As we look at the market today, Mike, clearly the market is growing much more slowly than we had anticipated, even as recently as pulling together our plan for 2010 and obviously providing the guidance for 2010. You know in this particular market it is sometimes challenging. We have less than perfect market information. It is not like the pharma business, where you got IMS data and you can track things in a much more definitive way. So it is a little bit elusive.*
>
> Our best guess is that the US market -- and let's just talk about the US market, because that is where most of this is centered -- it is probably growing no more than 1% or 2% right now. Okay? ***So we clearly overcalled the market growth. And I think one of the reasons that we did that is if you go back in time, let's say a year ago -- because our year-to-year comps, obviously are very -- a year ago, right now, we were having a very different discussion -- very robust results, frankly, in excess of what we had projected. And the challenge then at that point was how much did we interpret that to be more robust market growth and how much of that was share gains. And again, this gets to -- and this isn't an excuse -- it is just giving you the facts, and you know most of this -- less than perfect market information.***
>
> ***I think we interpreted our strength a year ago, late 2008 and early 2009, to be more a function of more significant market growth as opposed to, I think, we were gaining more share at that time, given the fact that one of the competitors was***

having some supply issues in the market. So I think that is a historical fact that is relevant.

The other thing was going on to the market in general, as you know, was we were moving, over the course of really about two years, from being in a fairly dramatic product shortage in the market to then moving more recently, of course, to adequate supply, even leading to the point where all of us now are adding sales resources and so on, as you know.

And then of course, mixed in with all of that was the balancing in the supply chain and the distribution channel, and ascertaining what was fundamental demand and what was really rebalancing of channel inventory became the third factor.

So simply -- just to summarize simply, we've overcalled the market growth. It is growing at a lesser rate, and I think there are some environmental factors, clearly, that are leading to that, which I won't expand on. We can follow up on that if you'd like.

The market is growing much slower than what we had anticipated. As I acknowledged on our last call, we've lost some market share. It is largely share, I think, that we gained in late 2008 and early 2009. And since our last call, we've lost, I think, somewhat more market share as well.

As you know, we are the premium brand, as I had mentioned in my prepared comments. So we are -- we have and we are going to continue to selectively touch up prices where necessary to keep our volume, and we are doing that, all at the same time, as you know, we are expanding sales force.

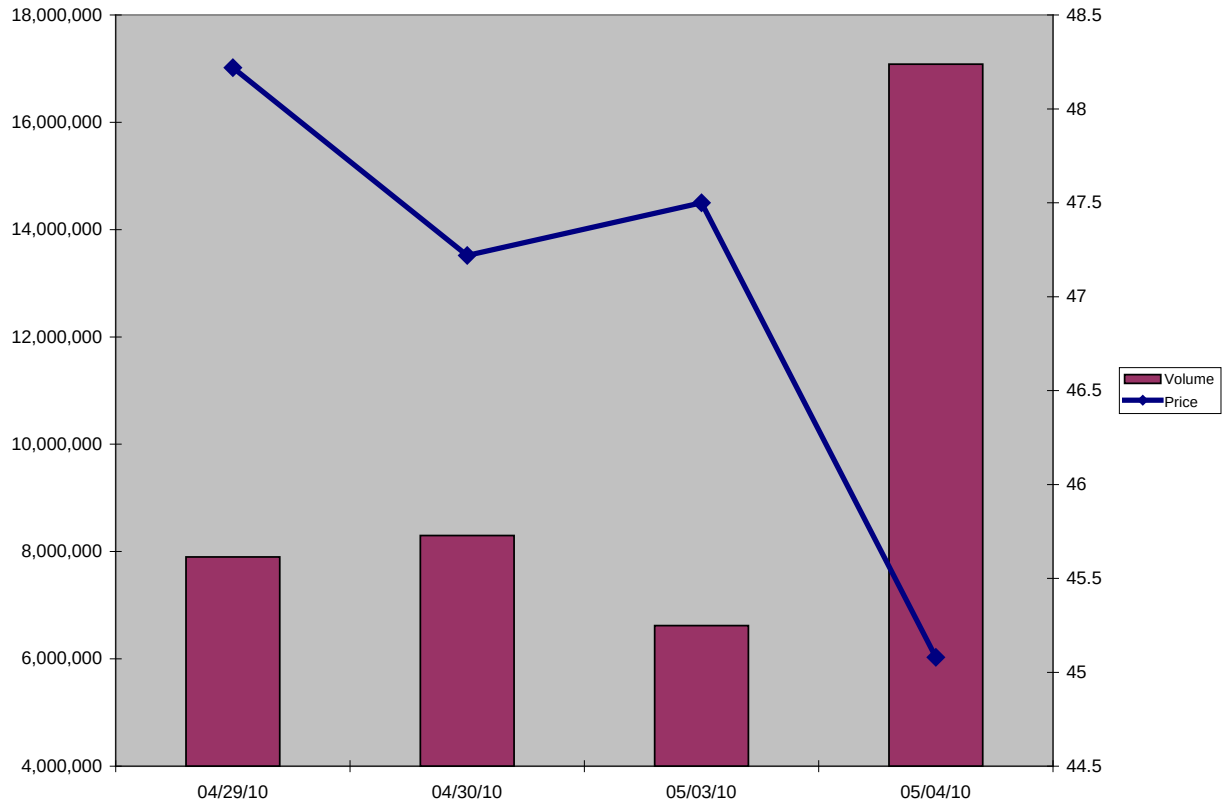
So that is probably about the best I can do in addressing the various dynamics, of which there are several. And on all fronts, we have less than perfect information.

But -- and so going forward, low single-digit market growth in the US market; probably higher growth outside the US, as you know. I really don't want to get into the pricing discussion for reasons that you all understand, beyond what I've already commented on.

269. Also on April 22, 2010, *The Wall Street Journal* published an online article, "Baxter Cuts Outlook on Plasma-market Slowdown." The article discussed the slowed market for plasma-based products, stating the "slowdown stoked fresh uncertainty about a hard-to-predict business that has long been a source of investor concern, and is a key component in Baxter's largest business unit." The article further stated that the slowdown "could have a lasting impact for Baxter, which felt the plasma market was on firmer footing when it issued 2010 guidance three months ago, even after some signs of fourth-quarter softness."

270. In response to the Company's first quarter financial results, William Blair & Company, issued an analyst report downgrading Baxter to "Market Perform," as a results of the "uncertainty regarding when we will get clarity on plasma-derived protein market growth, pricing, and share trends." Further, in reaction to management's comments on slowed market growth, analysts at William Blair & Company has reduced confidence that "pricing will stabilize in the near term."

271. On this partial revelation of the truth regarding Baxter's financials and future business prospects, the price of Baxter common stock collapsed $7.82 per share, or approximately 13%, to close at $51.13 per share. This decline was the largest one-day decline in the Company's stock over the past seven years, as shown in the chart below:



272. Following Baxter's first quarter earnings release, AvondalePartners, LLC commented that "[a]bout a year ago, what management interpreted as overall market growth, was more likely

market share gains, and when Baxter started losing some share (as it pointed out on its last call), the result was further deterioration than anyone expected."

273. The statements referenced in ¶268 were each materially false and misleading when made for reasons set forth in ¶202 and the factual detail contained throughout this Complaint. In addition, the statements referenced in ¶268 were materially false and misleading when made because they represented and/or omitted adverse facts which then existed and disclosure of which was necessary to make the statements not false and/or misleading. The true facts, which were known to or recklessly disregarded by each of the Defendants, were:

- Defendants omitted the material fact that as of the date of these statements, the Company had already submitted to the FDA – on April 8, 2010 – a proposed correction schedule for Baxter's ongoing attempt to remediate the Colleague pumps. Despite telling the FDA that Baxter needed until 2013 to remediate the Colleague – some seven years after entry of the Consent Decree – Defendants omitted this information and failed to correct their prior false and misleading statements that the Company planned to remediate the Colleague in 2010.

- Defendants knew the Company could not comply with the terms of the Consent Decree for at least several more years, that the Company's internal controls and quality systems had prevented it from achieving an earlier remediation, and that the Company was still submitting only "roadmaps" – which were universally rejected – to the FDA. On top of the foregoing, the Company was no longer in active dialogue with the FDA's Office of Compliance regarding the Colleague, which was a clear signal to the Company that the FDA was implementing additional punitive measures pursuant to the terms and conditions of the Consent Decree.

- Rather than "miscalling" the plasma market and its capacity for growth, the reality was that Defendants had misled the market. Defendants knew the key to the Company's ongoing plasma market success was its ability to manipulate supply and control prices, which led to artificially inflated margins. From the start of the Class Period, however, Defendants were fully aware that Baxter's ability to manipulate the market had been materially compromised. The disclosures on April 22, 2010 reflected the manifestation of Defendants' fraud catching up to Baxter, which was a far cry from what Defendants labeled as merely miscalling the market.

274. On May 3, 2010, Baxter issued a press release announcing it was recalling all Colleague pumps in the United States. The press release stated in relevant part, as follows:

> *Baxter Healthcare Corporation today announced that it will recall COLLEAGUE infusion pumps from the U.S. market pursuant to an order under its existing June*

> *2006 consent decree with the U.S. Food and Drug Administration (FDA). Baxter will work with the FDA to ensure that the recall process provides customers appropriate alternatives for supporting patients' needs.*
>
> As previously disclosed, Baxter entered into a consent decree with FDA under which the company has been pursuing remediation of the infusion pumps. The decree permits FDA to require the recall of the pumps, and FDA has communicated to the company that it will require such a recall, with the company providing monetary consideration or replacement pumps to customers on a timeline to be determined with FDA and based on medical need. Baxter intends to work with FDA to minimize disruption to healthcare facilities using COLLEAGUE pumps. Baxter anticipates that, among alternatives to be provided to customers, the company will offer to exchange Baxter's Sigma SPECTRUM infusion pumps for COLLEAGUE infusion pumps without charge to customers.
>
> The consent decree permits Baxter to propose alternative actions to achieve the FDA's objectives under the decree, which the company intends to do. The final nature of the recall and offer to customers remain subject to that ongoing dialogue. Once final, Baxter will notify customers and make information available on www.baxter.com.
>
> Notwithstanding that uncertainty, the company currently anticipates that it will record a pre-tax special charge of $400 to $600 million in the first quarter for the reasonably estimable cost of the recall. The company is not otherwise revising its earnings guidance for the year in connection with the recall.

275. Subsequently, on May 3, 2010, the FDA issued a statement concerning Baxter's recall of the Colleague pumps, which stated in part:[15]

> *The U.S. Food and Drug Administration sent a letter to Baxter Healthcare Corp. on April 30 ordering the company to recall and destroy all of its Colleague Volumetric Infusion Pumps (Colleague pumps) currently in use in the United States. This action is based on a longstanding failure to correct many serious problems with the pumps.* The FDA believes there may be as many as 200,000 of those pumps currently in use.
>
> *Additionally, the FDA is ordering the company to provide refunds to customers or replace pumps at no cost to customers [to] help defray the cost of replacement.*
>
> Infusion pumps are devices that deliver fluids, including nutrients and medications, into a patient's body in a controlled manner They are widely used in hospitals, other

[15] A complete copy of the FDA's May 3, 2010 statement is available on the FDA's website at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm210664.htm (last visited April 15, 2011).

clinical settings and, increasingly, in the home because they allow a greater level of accuracy in fluid delivery.

Hospitals and other users of Baxter's Colleague pumps will be receiving further instruction and information from Baxter and the FDA regarding their transition.

The FDA has been working with Baxter since 1999 to correct numerous device flaws. Since then, Colleague pumps have been the subject of several Class I recalls for battery swelling, inadvertent power off, service data errors, and other issues.

In June 2006, the FDA was [sic] obtained a consent decree of permanent injunction in which Baxter agreed to stop manufacturing and distributing all models of the Colleague pump until the company corrected manufacturing deficiencies and until devices in use were brought into compliance. Since then, Baxter has made numerous changes to the Colleague pumps but these changes have not corrected the product defect leading to the permanent injunction.

On April 8, 2010, Baxter submitted a proposed correction schedule to the FDA that stated that Baxter did not plan to begin the latest round of corrections to the adulterated and misbranded pumps until May 2012. The proposal also stated that Baxter does not anticipate completion of the proposed corrections until 2013. On that schedule, a device with known safety concerns would remain in use on patients needing specialized care until 2013. FDA found this proposal unacceptable. The 2006 consent decree gave FDA authority to take any action it deemed appropriate. The FDA has determined that this action is necessary, as Baxter has failed to adequately correct, within a reasonable timeframe, the deficiencies in the Colleague infusion pumps still in use.

Therefore the FDA is now ordering Baxter to:

- Recall and destroy all Colleague infusion pumps.
- Reimburse customers for the value of the recalled device
- Assist in finding a replacement for these customers.

Infusion pumps, including the Baxter Colleague models, have been the source of persistent safety problems. In the past five years, the FDA has received more than 56,000 reports of adverse events associated with the use of infusion pumps. Those events have included serious injuries and more than 500 deaths. Between 2005 and 2009, 87 infusion pump recalls were conducted to address identified safety concerns, according to FDA data.

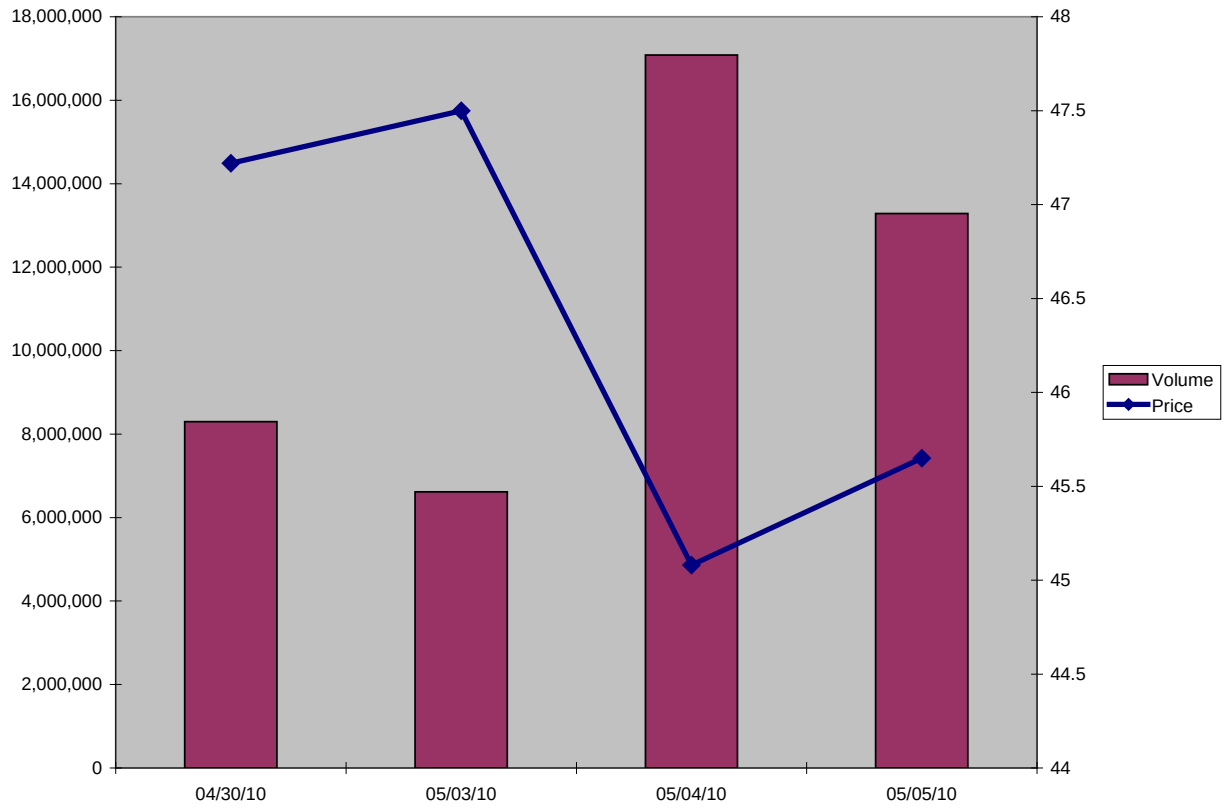
An FDA analysis of these adverse events has uncovered software defects, user interface problems and mechanical and electrical failures. Problems with infusion pumps are not confined to one manufacturer or one type of device.

In response, last month the FDA announced a new initiative to address safety problems associated with infusion pumps. As part of its initiative, the FDA is moving to establish additional premarket requirements manufacturers will be expected to meet,

> in part through static testing in FDA's facilities before device submissions. The FDA is also holding a May public workshop on infusion pump design, and the agency is raising public awareness of the issue among health care workers and patients.

276. On May 4, 2010, ABC News published an article, "Baxter Drops as FDA Mandates Colleague Pump Recall." The article discussed how the price on Baxter common stock fell to a three-year low in response to the FDA's directive to "recall and destroy its Colleague infusion pumps." According to the article, an analyst at Credit Suisse said "the recall would help competitors CareFusion and Hospira, and while Baxter maintained its annual guidance," the analyst cut estimates over the next three years.

277. On this news, the price of Baxter common stock dropped another $2.42, or 5.09%, to close at $45.08 per share on May 4, 2010, on heavy volume of more than 17 million shares traded, as demonstrated by the following chart:



278. The true facts, which were known by the defendants but concealed from the investing public during the Class Period, were as follows:

(a) The failure of a proposed merger between Baxter's two largest competitors was resulting in increased supplies of plasma and increasing pricing pressure;

(b) Baxter failed to disclose known trends and uncertainties related to the industry operations and the market for its plasma-derivative products, including that the boost in market share and gross profit margin it had experienced prior to the failure of the merger between CSL and Talecris was only temporary and the Company would be unable to sustain the benefits it had enjoyed upon the failure of the merger;

(c) Baxter's revenue guidance for 2010 related to its financial performance, specifically in its BioScience business and for its plasma-derivative products, lacked a reasonable basis when made;

(d) Baxter had represented to investors that its long range plan related to its BioScience division was revenue growth in the 7% to 9% range, when in fact the Company was experiencing a loss in market share and pricing pressures related to its plasma-derivative products, such that Baxter's forecasts based on the long range plan for the BioScience division lacked a reasonable basis; and

(e) Defendants failed to disclose, among other facts set forth in this Complaint, that Baxter was: (i) not complying with the June 2006 Consent Decree; (ii) not able complete remediation of the Colleague pump in 2010; (iii) required to conduct clinical trials on the Colleague that would take years to complete; (iv) incapable of submitting a 510(k) for Colleague remediation (the Company had no clinical data); and (v) that the FDA consistently told Baxter (including Parkinson) that the Company's timeline for Colleague remediation was unacceptable.

279. As a result of Defendants' false statements, Baxter's stock traded at artificially inflated levels during the Class Period. When the truth about Baxter's actual business prospects going forward was revealed, Baxter's stock price fell nearly 27% from its Class Period high, from $61.71 per

share on January 14, 2010, to close at $45.08 per share on May 4, 2010. This drop removed the inflation from Baxter's stock price, causing real economic loss to investors who had purchased the stock during the Class Period.

A. Post-Class Period Events

280. On May 10, 2010, Argus downgraded Baxter to hold based on the Company's "challenging outlook." Argus lowered the Company rating, stating "as we are concerned about weak plasma proteins and antibody therapy, two key medication categories within the BioScience segment." Further, Argus cut its EPS estimates to $3.90 from $4.23 for 2010 and to $4.25 from $4.65 for 2011.

281. On July 13, 2010, the FDA issued its final order requiring Baxter to take specific steps to carry out the April 2010 recall of the Colleague pump and to provide customers with a refund, replacement pump, or lease termination. The FDA also mandated that Baxter complete the recall and replace or refund the Colleague pumps by July 14, 2012. Baxter is also responsible for providing a transition guide for its customers affected by the recall.

X. ADDITIONAL SCIENTER ALLEGATIONS

282. As alleged herein, Defendants acted with scienter in that they knew or disregarded with severe recklessness that the public documents and statements, issued or disseminated in the name of the Company, were materially false and misleading, knew that such statements or documents would be issued or disseminated to the investing public, and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail throughout this complaint, Defendants, by virtue of their receipt of information reflecting the true facts regarding Baxter, their control over, and/or receipt and/or modification of Baxter's allegedly materially misleading misstatements and/or their associations with the Company which made them

privy to confidential proprietary information concerning Baxter, participated in the fraudulent scheme alleged herein.

283. Defendants knew and/or disregarded with severe recklessness the falsity and misleading nature of the information that they caused to be disseminated to the investing public. The ongoing fraudulent scheme described in this complaint could not have been perpetrated over a substantial period of time, as has occurred, without the knowledge and complicity of the personnel at the highest level of the Company, including each of the Individual Defendants.

XI. APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD ON THE MARKET DOCTRINE

284. At all relevant times, the market for Baxter common stock was an efficient market for the following reasons, among other things:

(a) Baxter stock met the requirements for listing, and were listed and actively traded on the NYSE, a highly efficient and automated market;

(b) As a regulated issuer, Baxter filed periodic public reports with the SEC; and

(c) Baxter regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services.

285. As a result, the market for Baxter common stock promptly digested current information regarding Baxter from all publicly-available sources and reflected such information in the price of Baxter stock. Under these circumstances, all purchasers of Baxter common stock during the Class Period suffered similar injury through their purchase of Baxter common stock at artificially inflated prices and a presumption of reliance applies.

XII. LOSS CAUSATION

286. During the Class Period, as detailed herein, Defendants engaged in a scheme to deceive the market and a course of conduct that artificially inflated Baxter's stock price throughout the Class Period. These acts and omissions operated as a fraud or deceit on Class Period purchasers of Baxter stock by misrepresenting the Company's business success and future business prospects, including, but not limited to, misrepresentations regarding Baxter's plasma-derivative products business. Additionally, instead of truthfully disclosing that Baxter was incapable and unwilling to remediate its Colleague pump – and thus would not be in a position to comply with the Consent Decree for at least several years after the close of the Class Period – Defendants assured investors that Baxter was working diligently with the FDA to remediate any outstanding problems with the Colleague pumps, and that it would resolve those issues during 2010.

287. As a result of Defendants' fraudulent conduct, the prices at which Baxter stock traded were artificially inflated during the Class Period. When Plaintiff and other members of the Class purchased their Baxter securities, the true value of such securities was substantially lower than the prices actually paid by Plaintiff and the other members of the Class.

288. By misrepresenting the success of the Company's business and concealing its improprieties, Defendants presented a misleading picture of Baxter's business and future business prospects. These claims of future profitability and possibilities of future growth caused and maintained the artificial inflation in Baxter's stock price throughout the Class Period until the truth was partially revealed to the market, through the two partial disclosures described herein.

289. As a result of Defendants' materially false and misleading statements and documents, as well as the adverse, undisclosed information known to the Defendants, Plaintiff and other members of the Class relied, to their detriment, on such statements and documents, and/or the integrity of the market, in purchasing their Baxter stock at artificially inflated prices during the Class

Period. Had Plaintiff and the other members of the Class known the truth, they would not have taken such actions.

290. As explained herein, Defendants' materially false statements directly or proximately caused, or were a substantial contributing cause of, the damages and economic loss suffered by Plaintiff and other members of the Class. These statements served to maintain the artificial inflation in Baxter's stock price throughout the Class Period and until the truth leaked into and was partially revealed to the market, at which time the prior inflation came out of the stock.

291. Defendants' false and misleading statements had their intended effect and directly and proximately caused, or were a substantial contributing cause of, Baxter's stock trading at artificially inflated levels, reaching as high as $67.71 per share on January 14, 2010.

292. Nevertheless, the market's expectations were ultimately corrected on April 22, 2010 and May 3, 2010, when Defendants were: (i) forced to publicly disclose that the Company was reducing its 2010 outlook due to loss of market share, decreased demand, and compressed margins in its plasma-derivative products business; and (ii) forced by the FDA to recall its Colleague pumps for ongoing and substantial inability to comply with the terms of the Consent Decree. These partial disclosures had a devastating effect on the price of Baxter common stock, as it fell by as much as 13% to close at $51.13 per share on April 22, 2010 (the largest drop in seven years) and dropped another 5%, to close at $45.08 per share on May 4, 2010. The cumulative impact of these declines was that the price of Baxter stock fell 27% from its Class Period high, causing substantial harm to investors who suffered hundreds of millions of dollars in losses as the artificial inflation generated by Defendants' fraud was removed.

293. The timing and magnitude of the declines in Baxter common stock negate any inference that the losses suffered by Plaintiff and other Class members were caused by changed market conditions, macroeconomic or industry factors, or Company-specific facts unrelated to the

Defendants' fraudulent conduct. The economic loss, *i.e.*, damages, suffered by Plaintiff and other members of the Class was a direct result of Defendants' fraudulent scheme to artificially inflate the price of Baxter common stock and its subsequent decline in value as Defendants' prior misrepresentations and other ongoing fraudulent conduct were revealed, market expectations were corrected, and the artificial inflation came out of the price of Baxter common stock.

294. In addition, the decline in price of Baxter common stock was a natural and probable consequence of Defendants' fraud and should have been foreseen by Defendants in light of the attending circumstances. The market reactions to the disclosure of Baxter's true financial condition and future business prospects were foreseeable to Defendants and well within the "zone of risk" concealed by Defendants' fraudulent conduct.

XIII. NO SAFE HARBOR

295. The federal statutory safe harbor provision, which provides for forward-looking statements under certain circumstances, does not apply to any of the allegedly false statements pleaded in this complaint. Many of the specific statements pleaded herein were not identified as "forward-looking statements" when made. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of Baxter who knew that those statements were false when made. Moreover, to the extent that Defendants issued any disclosures designed to "warn" or "caution" investors of certain "risks," those disclosures were also false and misleading since they did not disclose that

Defendants were actually engaging in the very actions about which they purportedly warned and/or had actual knowledge of material adverse facts undermining such disclosures.

XIV. COUNT 1: FOR VIOLATIONS OF SECTION 10(b) OF THE EXCHANGE ACT AND RULE 10b-5 PROMULGATED THEREUNDER AGAINST ALL DEFENDANTS

296. Plaintiff repeats and realleges the allegations set forth above as though fully set forth herein. This claim is asserted against all Defendants.

297. During the Class Period, Baxter and the Individual Defendants, and each of them, carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Baxter common stock; and (iii) cause Plaintiff and other members of the Class to purchase Baxter stock at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Baxter and the Individual Defendants, and each of them, took actions set forth herein.

298. These Defendants: (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operate as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Baxter common stock in violation of §10(b) of the Exchange Act and Rule 10b-5. These Defendants are sued as primary participants in the wrongful and illegal conduct charged herein. The Individual Defendants are also sued as controlling persons of Baxter, as alleged below.

299. In addition to the duties of full disclosure imposed on Defendants as a result of their making affirmative statements and reports, or participating in the making of affirmative statements and reports, or participating in the making of affirmative statements and reports to the investing

public, they each had a duty to promptly disseminate truthful information that would be material to investors in compliance with the integrated disclosure provisions of the SEC as embodied in SEC Regulation S-X (17 C.F.R. § 210.01 et seq.) and S-K (17 C.F.R. §229.10 et seq.) and other SEC regulations, including accurate and truthful information with respect to the Company's operations, surveillance, financial condition and operational performance, so that the market prices of the Company's common stock would be based on truthful, complete and accurate information.

300. Baxter and each of the Individual Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about the business, business practices, performance, operations and future prospects of Baxter as specified herein.

301. These Defendants each employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Baxter's value and performance, financial and operational growth, which included the making of, or the participation in the making of, untrue statements of material facts and omitting to state necessary facts in order to make the statements made about Baxter and its business operations and future prospects in light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of Baxter common stock during the Class Period.

302. Each of the Individual Defendants' primary liability, and controlling person liability, arises from the following facts: a) each of the Individual Defendants was a high-level executive and/or director at the Company during the Class Period; b) each of the Individual Defendants, by virtue of his responsibilities and activities as a senior executive officer and/or director of the

Company, was privy to and participated in the creation, development and reporting of the Company's financial performance, projections and/or reports; and c) each of the Individual Defendants was aware of the Company's dissemination of information to the investing public which each knew or disregarded with severe recklessness was materially false and misleading.

303. Each of these Defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with severely reckless disregard for the truth in that each failed to ascertain and to disclose such facts, even though such facts were available to each of them. Such Defendants' material misrepresentations and/or omissions were done knowingly or with severe recklessness and for the purpose and effect of concealing Baxter's operating condition and future business prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' misstatements of the Company's financial condition and performance throughout the Class Period, each of the Individual Defendants, if he did not have actual knowledge of the misrepresentations and omissions alleged, was severely reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false and misleading.

304. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market prices of Baxter common stock were artificially inflated during the Class Period. In ignorance of the fact that market prices of Baxter common stock were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trade, and/or on the absence of material adverse information that was known to or disregarded with severe recklessness by Defendants but not disclosed in public statements by Defendants during the Class Period, Plaintiff and the other members of the Class acquired Baxter stock during the Class Period at artificially high prices and were damaged thereby, as evidenced by,

among others, the stock price declines on or about April 22-23, 2010 and May 3-4, 2010, when the artificial inflation was released from Baxter stock.

305. At the time of said misrepresentations and omissions, Plaintiff and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiff and the other members of the Class and the marketplace known of the true performance, future prospects and intrinsic value of Baxter, which were not disclosed by Defendants, Plaintiff and other members of the Class would not have purchased or otherwise acquired their Baxter common stock during the Class Period, or they would not have done so at the artificially inflated prices which they paid.

306. By virtue of the foregoing, Baxter and the Individual Defendants have each violated §10(b) of the Exchange Act, and Rule 10b-5 promulgated thereunder.

307. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period, as evidenced by, among others, the stock price declines on or about April 22-23, 2010 and May 3-4, 2010, when the artificial inflation was released from Baxter stock.

XV. COUNT II: FOR VIOLATIONS OF SECTION 20(a) OF THE EXCHANGE ACT AGAINST THE INDIVIDUAL DEFENDANTS

308. Plaintiff repeats and realleges the allegations set forth above as though fully set forth herein. This claim is asserted against the Individual Defendants.

309. Each of the Individual Defendants acted as a controlling person of Baxter within the meaning of §20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions with the Company, participation in and/or awareness of the Company's operations and/or intimate knowledge of the Company's fraudulent marketing and promotions and actual performance, each of the Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination

of the various statements which Plaintiff contends are false and misleading. Each of the Individual Defendants was provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by Plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

310. In addition, each of the Individual Defendants had direct involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations alleged herein, and exercised the same.

424. As set forth above, Baxter and the Individual Defendants each violated §10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their controlling positions, each of the Individual Defendants is liable pursuant to §20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's stock during the Class Period, as evidenced by, among others, the stock price declines on or about April 22-23, 2010 and May 3-4, 2010, when the artificial inflation was released from Baxter stock.

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

(a) Determining that this action is a proper class action and designating Lead Plaintiff as a class representative under Rule 23 of the Federal Rules of Civil Procedure;

(b) Awarding compensatory damages in favor of Plaintiff and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

(c) Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

(d) Such other and further relief as the Court may deem just and proper.

XVI. JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

DATED: April 15, 2011

MILLER LAW LLP
MARVIN A. MILLER
MATTHEW E. VAN TINE
LORI A. FANNING

/s/ Marvin A. Miller
MARVIN A. MILLER
115 S. LaSalle Street, Suite 2910
Chicago, IL 60603
Telephone: 312/332-3400
312/676-2676 (fax)

ROBBINS GELLER RUDMAN
& DOWD LLP
DAVID J. GORGE
ROBERT J. ROBBINS
120 East Palmetto Park Road, Suite 500
Boca Raton, FL 33432
Telephone: 561/750-3000
561/750-3364 (fax)

SUGARMAN & SUSSKIND
ROBERT SUGARMAN
100 Miracle Mile, Suite 300
Coral Gables, FL 33134
Telephone: 305/529-2801
305/447-8115 (fax)

Attorneys for Plaintiff

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on April 15, 2011, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system. The electronic case filing system sent a "Notice of Electronic Filing" to the attorneys of record who have consented in writing to accept this notice as service of this document by electronic means.

/s/ Marvin A. Miller
Marvin A. Miller